Title: Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers

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Declared interests of the authors

Description of any pecuniary relationship with the company, both personal and of the EAC. Please refer to NICE's Code of Practice for declaring and dealing with conflicts of interests.
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Rider on responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Contents

ABBREVIATIONS

Term	Definition
AE	Adverse event
ANZCTR	Australian New Zealand Clinical Trials Registry
AWMA	Australian Wound Management Association
BMI	Body Mass Index
BMJ	British Medical Journal
CADTH	Canadian Agency for Drugs and Technologies in Health
CAET	Canadian Association for Enterostomal Therapy
CASP	Critical appraisal skills programme
CEA	Cost-effectiveness analysis
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CONSORT	Consolidated Standards of Reporting Trials
CPCI	Conference Proceedings Citation Index
CRD	Centre for reviews and dissemination
DTI	Deep tissue injury
EAC	External assessment centre
ED	Emergency department
EPUAP	European Pressure Ulcer Advisory Panel
EWMA	European Wound Management Association
FDA	U S Food and Drug Administration
HAPU	Hospital Acquired Pressure Ulcer
HTA	Health technology assessment
IAD	Incontinence-associated dermatitis
ICTRP	International Clinical Trials Registry Platform
ICU	Intensive care unit
ITT	Intention to treat
LOS	Length of stay
MODS	Multiple organ dysfunction syndrome
MTAC	Medical technologies advisory committee
MTEP	Medical technologies evaluation programme
NA	Not applicable
NDNQI	National Database of Nursing Quality Indicators
NHMRC	National Health and Medical Research Council
NHS	National Health Service
NHS EED	National Health Service economic evaluation database
NPUAP	National Pressure Ulcer Advisory Panel
NR	Not reported
NS	Not stated
OPCABG	Off-pump coronary artery bypass graft
PSA	Probabilistic sensitivity analysis
PU	Pressure ulcer
QOL	Quality of Life
RCT	Randomised controlled trial
RR	Relative risk
SAWC	Symposium on Advanced Wound Care
SC	Standard care
SCI	Spinal cord injury
SIRS	Systemic inflammatory response syndrome
SoC	Standard of care
UK	United Kingdom
US	United states
USA	United states of America
VAT	Value added tax
WHO	World Health Organisation
WOC	Wound, ostomy and continence

WOCN	Wound, ostomy and continence nurses
WUWHS	World Union of Wound Healing Societies

1 Executive Summary

Mepilex Border dressings are self-adherent, 5-layer foam dressings aiming to preventing the occurrence of pressure ulcers. They are used alongside standard protocols for pressure ulcer prevention. This report focuses on 2 variants of the dressing designed specifically for the heel and sacrum.

The company reviewed the literature and identified 34 studies reported across 35 publications. The company's eligibility criteria was not in full alignment with the scope. The EAC realigned the eligibility criteria with the NICE scope and conducted new searches to identify further relevant evidence. Following study selection, 13 studies reported across 23 publications were included by the EAC. The evidence comprised 4 RCTs and 9 nonrandomised comparative studies. The majority of studies compared Mepilex Border Sacrum dressings (plus standard care) with standard care alone for the prevention of pressure ulcers in 'at high risk' patients. There was limited comparative evidence for Mepilex Border Heel and Mepilex Border (applied to the sacrum) dressings. The included studies reported on few outcomes in relation to the scope, with pressure ulcer incidence most commonly reported. A meta-analysis indicated that the point estimate is in favour of Mepilex Border Sacrum dressings, the difference is not statistically significant (RR 0.51 [95% CI 0.22 to 1.18]).

An economic study set in Australia estimated cost savings with use of Mepilex Border Heel and Sacrum dressings. Neither the company nor the EAC identified any UK published economic studies on Mepilex Border Heel or Sacrum dressings. The company's *de novo* model captured the key cost elements of the condition and intervention. The EAC modified all input parameters to improve its applicability to the NHS. Following these revisions, the EAC estimated cost savings with Mepilex Border dressings of £19 per patient, with a probability of being cost saving estimated at 57%. However, deterministic sensitivity analysis demonstrated that these results were highly sensitive to changes in input parameters. An analysis of Mepilex Border Sacrum dressings only indicated lower decision uncertainty, with cost savings increased to £27 per patient and the probability of being cost saving to 81%. Cost-savings are increased where the baseline incidence of pressure ulcer with standard care increases. Wider benefits of reducing the pressure ulcer incidence include the impact on patients' quality of life and freeing up resources within the NHS.

To conclude, despite a relatively large body of clinical evidence, there remains uncertainty in the treatment effect of Mepilex Border dressings and consequently decision uncertainty. This uncertainty is lower in patients or settings with a relatively high baseline incidence of pressure ulcers and for the Mepilex Border Sacrum dressing intervention specifically.

2 Background

Throughout this report, the EAC makes reference to specific sections within the company's submission, which is a separate document. Where the EAC cites clinical experts, further information can be obtained from the EAC external correspondence log (NYEAC, 2018).

2.1 Overview and critique of company's description of clinical context

The company provided a description of the technology and its mechanism of action in Section 2 of the submission. A review of the clinical context of the technology (i.e. its place in the current patient pathway) was provided in Section 3, and the relevant national guidelines were described in Section 3.2. The EAC considers these sections to be well written, accurate, and informative. The following EAC summary is intended to add clarification to the company's description of the clinical context.

2.1.1 The technology

As described in Section 2.1 of the company submission, Mepilex Border dressings are self-adherent, multilayer foam dressings that include proprietary soft silicone technology (Safetac). They are available in various sizes and there are also variants that are specifically designed for use on the heel and sacrum, both of which are high risk areas for pressure ulcer formation (Section 2.1, Submission). The Mepilex Border Sacrum dressing is available in 3 sizes (15 x 15cm, 16 x 20cm, 22 x 25cm), and Mepilex Border Heel dressings is available in 2 sizes (22 x 23cm, 18.5 x 24cm). The 3 different Mepilex Border dressings are shown in Figure 2.1 to Figure *2.3*.

Figure 2.1: Mepilex Border dressing (for any part of the body)

Figure obtained from https://www.molnlycke.co.uk/products-solutions/mepilex/

Figure 2.2: Mepilex Border Sacrum dressing – available in 3 sizes

Figure obtained from https://www.molnlycke.co.uk/products-solutions/mepilex/

Figure 2.3: Mepilex Border Heel dressing – available in 2 sizes

Figure obtained from https://www.molnlycke.co.uk/products-solutions/mepilex/

The dressings are made up of 5 layers, the first of which is designed to reduce friction between skin and the dressing, with the other layers designed to cushion, prevent stretch or tear, absorb moisture and allow moisture to evaporate. The Safetac technology, contained in the layer closest to the skin is designed to mould to the skin without sticking to the moist wound, enabling the dressing to be easily peeled back and reapplied enabling multiple inspections of the skin site without needing to fully replace the dressing (Section 2.1, Submission). The silicone layer is also designed to not adhere to the surface of a wound and, therefore, the dressing may be removed without causing pain or trauma (Thomas 2007).

A 3-layer version of the dressing is also available, referred to as Mepilex dressings rather than Mepilex *Border* dressings. This 3-layer version, as well as only having 3 layers as oppose to 5, has no border so requires attaching using a second device such as tape or retention bandage. The scope issued by NICE (NICE scope, Section 1.1) specifies the technology under consideration to be Mepilex Border Heel and sacrum dressings. Therefore, the EAC deemed the 3-layer Mepilex dressings to be outside the scope of this

evaluation. However, Mepilex Border dressings (not specific to the heel or sacrum) were still considered to be in scope. The company's submission included studies assessing the 3-layer dressings within its evidence submission, which were subsequently excluded by the EAC.

Mepilex Border dressings can be used to treat a wide range of wound types, but the scope and company submission focusses specifically on their use for prevention of pressure ulcers of the sacrum and heel.

2.1.2 The condition – pressure ulcers

Pressure ulcers are localised injuries to the skin and/or underlying tissue as a result of pressure, or pressure in combination with shear (National Pressure Ulcer Advisory Panel 2014b). All patients are potentially at risk of developing a pressure ulcer, but typically they occur in a person confined to bed or a chair by illness (National Institute for Health and Care Excellence 2014a). Several risk factors exist that may increase the likelihood of developing a pressure ulcer, which include:

- Reduced mobility or immobility – pain is a warning signal that pressure has been exerted for too long, which normally triggers movement. Patients who are unable to move will require the help of someone else in order to do so.

- Lack of sensation – if pain signals are absent, patients may not be aware that damage is occurring and will not realise they should move. This includes anything which may impair sensation including unconsciousness, analgesia or alcohol/substance abuse.

- Nutritional status – it is widely accepted that undernourished people are at increased risk of pressure ulcer development.

- Compromised vascular supply – skin with compromised vascular supply may deteriorate more rapidly. Patients with peripheral arterial disease, or patients who experience events such as cardiac arrest or hypovolaemic shock may be at increased risk.

- Moisture – skin that is constantly or often moist is at increased risk of pressure ulcer.

- Friction and shear – these forces are additional to pressure and further hamper blood flow by stretching and contorting blood vessels. This is most commonly seen in the sacrum and heels, where patients may slide down a surface and use their heels to resist this movement (Guy 2012).

The Mepilex Border dressings aim to address only the moisture, friction and shear risk factors as well as reducing pressure against which patients sit, lie or lean.

In addition to the risk factors identified above, clinical experts also indicated the following to be risk factors for developing pressure ulcers: diabetes, dementia, significant cognitive impairment, tremors, leg spasms, leg oedema, critical illness, low or high BMI, terminal illness, extremes of age, previous history of pressure damage, and long theatre times.

Many pressure ulcers are preventable, and avoidable pressure ulcers are seen as a key indicator of the quality and experience of patient care. A 'Stop the Pressure' campaign managed by NHS Improvement has raised awareness of pressure ulcers and led to improvements in prevention and care in recent years. However, despite this, management of pressure ulcers remains a significant healthcare problem (NHS Improvement 2018b).

Pressure ulcers can range in severity from stage 1 to suspected deep tissue injury. NICE guidelines recommend the NPUAP-EPUAP 2009 ulcer classification system to categorise each pressure ulcer (National Pressure Ulcer Advisory Panel and European Pressure Ulcer Advisory Panel 2009). Clinical experts were in agreement that NPUAP-EPUAP classification system is used. This is discussed further in Table 2.1

Table 2.1: Pressure ulcer staging

Stage/category	Description
Stage I	Nonblanchable erythema. Intact skin with non-blanchable redness of a localised area. Area may be painful, firm, soft, warmer or cooler as compared to adjacent tissue
Stage II	Partial thickness skin loss. Presents as a shiny or dry shallow open ulcer with a red pink wound bed without slough or bruising, or as an intact or open/ruptured blister.
Stage III	Full thickness skin loss. Subcutaneous fay may be visible but bone, tendon or muscle are not exposed. Slough may be present but does not obscure depth of tissue loss. May include undermining and tunnelling.
Stage IV	Full thickness tissue loss. Exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. Often include undermining and tunnelling.
Unstageable	Depth unknown. Full thickness tissue loss in which the base of the ulcer is covered by slough (yellow, tan, grey, green or brown) and/or eschar (tan, brown or black) in the wound bed. Until enough slough/eschar is removed to expose the base of the wound, the true depth, and therefore stage, cannot be determined.
Suspected deep tissue injury	Purple or maroon localized area of discoloured intact skin or blood filled blister due to damage of underlying soft tissue. Area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue.

Pressure ulcers can have a significant impact on a patient's quality of life, and severely compromise all areas of patient functioning, affecting both physical and psychological dimensions. Pressure ulcers may cause physical restrictions to patients requiring them to adapt their usual lifestyle and routine, as well as causing pain. They can also influence self-esteem and self-concept which in turn can have social participation implications. Pressure ulcers can also lead to further health complications such as infection, extended hospital stays, restricted rehabilitation and restricted treatment options for other medical conditions (Gorecki et al. 2009, Gorecki et al. 2013).

2.1.3 Patient pathway: prevention

The NICE clinical guideline for the prevention and management of pressure ulcers (National Institute for Health and Care Excellence 2014a) recommends the following:

- Undertaking and documenting a risk assessment for all people admitted to secondary care, and reassessing for any change in clinical status. Risk assessment tools such as the Braden scale[1], the Waterlow score[2] or the Norton risk-assessment scale[3] should be considered to support clinical judgement. Clinical experts indicated that this assessment is usually carried out within 6 hours of admission or sooner, and recalculated with clinical change or at least weekly for lower risk patients, and daily for those at high risk.

- Regular skin assessment for people being assessed at high risk of pressure ulcer. Clinical experts indicated that frequency of skin assessment may vary in practice with some experts stating this is to be carried out twice daily or more often, and others stating once daily.

- Repositioning at least every 6 hours for people at risk, or every 4 hours for people at high risk of developing a pressure ulcer. Clinical experts agreed that at risk patients were generally repositioned every 4 to 6 hours, and high risk patients every 2 to 4 hours.

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1 Braden score can range from 6 to 23 with *lower* scores indicating a higher risk of developing a PU. A score of 9 or less indicates very high risk; between 10 and 12 high risk; between 12 and 14 moderate risk and above 15 mild or no risk.

2 Waterlow scores range from 1 to 64 with *higher* scores indicating a higher risk. Scores of 10 or more indicate at risk of PU; a score of 15 or more indicates high risk and a score of 20 or more indicates very high risk.

3 Norton ratings range from 20 (minimum risk) to 5 (maximum risk). Ratings less than 10 indicate very high risk, between 10 and 14 high risk, between 14 and 18 medium risk and greater than 18 low risk.

- Use of high-specification foam mattress or cushion for people admitted to secondary care. Experts indicated that these were used in all patients, with the addition of alternative mattresses such as alternating cell and low air loss.

- Considering use of strategies to offload heel pressure as needed for high risk people. Two experts indicated that their trust uses Parafricta Bootees, and 1 indicated they use foam troughs and Heel Pro offloading devices. Four experts indicated that foam dressings may be used in some cases.

- Considering using barrier creams in people at high risk of developing a moisture lesion or incontinence-associated dermatitis as identified by skin assessment. Two experts indicated that barrier creams were used, 1 expert indicated that emollients were used, and another indicated that Metainium ointment and Proshield skin protectants are used.

Experts also stated that patients are given an information leaflet on admission along with ongoing verbal education regarding management and prevention or pressure ulcers.

Mepilex Border dressings are used in addition to the prevention strategies detailed above for patients identified as at risk or at high risk of developing a pressure ulcer.

2.1.4 Patient pathway: treatment

The NICE clinical guideline for the prevention and management of pressure ulcers (National Institute for Health and Care Excellence 2014a) recommends the following for managing a pressure ulcer:

- Document the surface area of all pressure ulcers using a validated measurement technique (such as transparency tracing or photograph) if possible. Document an estimate of the depth of all pressure ulcers and the presence of undermining.

- Categorise each pressure ulcer using a validated classification tool such as the International NPUAP-EPUAP 2009 pressure ulcer classification system. Repeat and document each time the ulcer is assessed.

- Offer adults with a pressure ulcer a nutritional assessment, and nutritional supplements to those who have a nutritional deficiency. Provide nutrition information and advice to patients or their family/carers.

- Use high-specification foam mattresses for adults with a pressure ulcer, or consider use of a dynamic support surface where this is not sufficient. Consider a high-specification foam or equivalent pressure redistributing cushion for adults who use a wheelchair or sit for prolonged periods.

- Assess the need to debride a pressure ulcer and offer debridement if identified as needed.

- Offer systemic antibiotics if there is clinical evidence of systemic sepsis, spreading cellulitis or underlying osteomyelitis.

- Consider using a dressing that promotes a warm, moist wound healing environment to treatment grade 2, 3 and 4 pressure ulcers.

- Discuss with adults with a heel pressure ulcer a strategy to offload heel pressure as part of an individualised care plan.

2.1.5 Guidelines

Within Section 3.2 of its submission the company described 2 UK guidelines and 3 relevant international guidelines. Clinical experts were asked if any key guidelines were missing, but no further UK or relevant international guidelines (i.e. covering the UK) were identified (NYEAC, 2018). These guidelines are listed in

Table 2.2 and their scope and relevance to this report reported. The guideline of most relevance to this report is NICE clinical guideline (CG) 179 - pressure ulcers: prevention and management.

A Medtech Innovation Briefing on the Mepilex Border dressings [MIB124] is also available which summarises the available evidence.

Table 2.2: Summary of key clinical guidelines

Guideline	Scope and relevance
NICE CG179 - Pressure ulcers: prevention and management (National Institute for Health and Care Excellence 2014a) (relevant sections used to inform Section 2.1.3 and 2.1.4)	NICE guideline on the prevention and management of pressure ulcers in people with or at risk of pressure ulcers. The guideline does not cover the use of prophylactic dressings, but is otherwise highly relevant.
NICE Guidance 19 - Diabetic foot problems: prevention and management (National Institute for Health and Care Excellence 2016)	NICE guideline covering preventing and managing foot problems in children, young people and adults with diabetes. The guideline refers to CG179 for pressure ulcers and does not refer to prophylactic dressing use, hence is of limited relevance.
National Pressure Ulcer Advisory Panel (NPUAP) (National Pressure Ulcer Advisory Panel 2014a)	The panel includes experts from England and Wales. It recommends considering the use of a 5-layer prophylactic dressing on the sacrum and heel in addition to standard care.
Black et al. (Black J et al.)	The consensus panel includes experts from England and Wales. It recommends considering the use of a 5-layer prophylactic dressing on the sacrum, buttock and heel in addition to standard care.
World Union of Wound Healing Societies (WUWHS) Consensus Document (World Union of Wound Healing Societies 2016)	The panel includes experts from England and Wales. It recommends considering the use of a 5-layer prophylactic dressing in all areas of at risk skin if patients meet particular characteristics (typically lack of mobility).

2.2 Critique of company's definition of the decision problem

The EAC has completed Table 2.3 to critique the company's definition of the decision problem.

Table 2.3: Relevance of submission to scope

Decision problem	Company submission	Matches decision problem? (Y/N/partially)	EAC comment
Population	Patients at risk of developing pressure ulcers (i.e. patients with <= category 1 pressure ulcers as defined by NPUAP et al. 2014 or an equivalent validated scale) with no signs of established pressure damage in an acute or aged care setting.	Partially	The company expanded the scope to include patients in an aged care setting. The company limited the population to patients 'at risk' of developing pressure ulcers as defined using a validated assessment scale (e.g. NPUAP 2014). Within this report, the EAC has considered the population included within the scope only.
Intervention	Mepilex Border Heel dressing or Mepilex Border Sacrum dressing or both dressings used as an adjunct to standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers.	Partially	The company expanded the scope to include both Mepilex Border dressing (not specific to heel and sacrum) and the 3-layer Mepilex dressing. Within this report, the EAC has included Mepilex Border Heel dressings, Mepilex Border Sacrum dressings and Mepilex Border dressings when cut to size for use on the heel or sacrum. The 3-layer Mepilex dressing and dressings used on other sites of the body have not been considered.
Comparator(s)	Standard NHS clinical practice for patients considered 'at risk' of pressure ulcers. This includes: • Risk assessment with validated scale • Skin assessment • Frequent repositioning (at least 6 hourly in people considered to be at risk and 4	Partially	The definition of standard care varies across jurisdictions and therefore across studies. As such the components of standard care are not always aligned with those described in the scope. These limitations are discussed when the external validity of the clinical studies is described in Section 3.5.

Decision problem	Company submission	Matches decision problem? (Y/N/partially)	EAC comment
	hourly in people considered to be at high risk) • Pressure redistribution using devices such as high specification foam mattress or pressure redistributing cushions. • Other dressings or skin applications to prevent pressure ulcers • Information • Barrier cream (specified situations)		
Outcomes	The outcome measures to consider include: • Incidence of developing pressure ulcers • Incidence of skin breakdown at the heel and sacrum • Stage of pressure ulcer developed (stage I – IV, unstageable) • Level of patient satisfaction • Additional length of hospital stay as a result of pressure ulcers including ICU and conventional ward bed days • Patient compliance with pressure ulcer prevention strategies • Level of pain and discomfort and impact on quality of life. • Complications avoided from pressure ulcer prevention e.g. infection, abscess, septicaemia, bone infections, meningitis. • Ease of use of product • Device-related adverse events	Partially	Outcomes were included and consistent with the published scope where relevant data were available. The included studies did not report any relevant data for the underlined outcomes.
Cost analysis	Comparator(s): Standard care (as listed in scope) Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long	Y	The comparator in the analysis is standard care. Limited information is provided on what standard care constitutes and how this compares with the NHS.

Decision problem	Company submission	Matches decision problem? (Y/N/partially)	EAC comment
	to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.		
Subgroups	None included in scope	N/A	N/A

Special considerations, including issues related to equality

The scope reported that "the device is likely to be beneficial to diabetic patients who may be at an increased risk of foot ulcers, patients who have had spinal injuries and people with restricted mobility. These groups of patients may be considered disabled if their conditions have a long term and substantial effect on their daily lives. Disability is a protected characteristic covered by the Equality Act 2010."

Both the company's submission and this report considered groups at high risk of pressure ulcers including diabetic patients, patients who have had spinal injuries, and people with restricted mobility. No selective advantages or disadvantages to these patients were identified, nor the potential for the guidance to cause unlawful discrimination or not promote equality.

3 Clinical evidence

3.1 Critique of and revisions to the company's search strategy

The search methodology used by the company to retrieve relevant clinical evidence from the published literature and unpublished sources was described in Section 7.1 of the submission. The full strategies for the published literature search were provided in Section 10.9, Appendix 1 of the submission. The reported search methodology for published and unpublished evidence had some limitations which could potentially have impacted on search sensitivity and the identification of relevant evidence. The limitations related to both the bibliographic search strategy and the selection of sources to search. The EAC was not able to replicate the company's search for published evidence due to lack of access to the interface used by the company (ProQuest Dialog). The company's strategies were translated for and run in the Ovid interface; this approximated a re-running of the company's searches. These searches retrieved 170 records. After deduplication, 124 records remained for assessment. The company's searches for unpublished evidence were conducted using internal company sources. It was, therefore, not possible for the EAC to replicate the company's searches for unpublished evidence. Given that the EAC was unable to fully replicate the company's search methodology, and because the reported methodology had limitations which could potentially have impacted on search sensitivity, the EAC conducted a *de novo* literature search to identify evidence.

The EAC search was conducted in a range of resources containing details of published, unpublished and ongoing research. The EAC search retrieved 2,073 records. After deduplication 1,209 records remained. Of the 1,209 records, 91 were duplicates of records identified in the re-run company's searches. The EAC searches, therefore, identified 1,118 unique records for assessment. In

total, across both the re-run company's clinical searches and the EAC *de novo* searches, 2,243 records were retrieved and 1,242 remained for assessment after deduplication (see PRISMA Flow Diagram in Appendix A). A full critique of the company's search methods, details of the re-run company's searches and details of the EAC's *de novo* search methods are provided in Appendix A.

3.2 Critique of the company's study selection

The company identified 203 records from its literature search, of which 35 studies were identified for further evaluation through retrieval of full-text publications. Nine unpublished studies were also identified through hand searching of internal company resources.

The company sifted the studies identified by the literature search according to the criteria reported in Table B1 of the submission. The company did not report in its submission whether single or double independent study selection was undertaken. However, in response to questions asked by the EAC, the company confirmed that a single reviewer screened the records (see correspondence log).

The eligibility criteria reported by the company were not in full alignment with the scope. The company limited the population to people at risk of developing pressure ulcers (i.e. patients with <= category 1 pressure ulcers as defined by NPUAP et al. (2014) or an equivalent validated scale) with no signs of established pressure damage. Further, the company broadened the population to accommodate studies of patients in other care settings as well as acute care. The eligible intervention was broadened by the company to include any type of Mepilex Border dressing to assist with pressure ulcer prevention. Eligible study designs considered by the company included systematic reviews, randomised controlled trials, non-randomised studies, observational cohort studies and qualitative studies. The company reported that databases were searched from 2001 onwards, because this was the year that Mepilex dressings were introduced. There were no restrictions placed on language.

Based on the selection criteria, the company included 34 studies reported across 35 records. This included:

- Five RCTs, including 4 published (Aloweni et al. 2017, Kalowes et al. 2016, Bao and Ji 2010, Santamaria et al. 2015a) and 1 unpublished (Santamaria 2018). Since the company submitted its report, a full publication has become available for Santamaria 2018 (Santamaria et al. 2018).

- 22 observational studies, including 14 published (Bateman and Roberts 2013, Brindle 2010, Brindle and Wegelin 2012, Chaiken 2012, Cubit et al. 2013, Johnstone and McGown 2013a, Koerner 2011, Padula 2017, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Sullivan 2015, Walsh et al. 2012, Yoshimura et al. 2016) and 8 unpublished (Baker 2014, Daukste 2013, Edwards and Lynch 2014, Gentry and Wright 2010, Haisley et al. 2015, Lientz 2013, Muldoon et al. 2010, Jin 2018).

- Seven systematic reviews (Black J et al., Clark et al. 2014, Cornish 2017, Huang et al. 2015, Moore and Webster 2013, National Pressure Ulcer Advisory Panel 2014a, Tayyib and Coyer 2016),all published.

The company used the PRISMA flow diagram to report on the studies identified (see Section 7.2.2, Submission).

The EAC reassessed the studies included by the company against the selection criteria. Based on this exercise, the EAC concluded that the following 11 studies should not have been included:

- One RCT (Bao and Ji 2010). This trial would have been excluded due to an ineligible population.

- Three comparative observational studies (Haisley et al. 2015, Koerner 2011, Padula 2017). Haisley 2015 and Koerner 2011 would have been excluded by the EAC due to insufficient detail reported about the population and intervention. Padula 2017 would have been excluded as an ineligible study design.

- Four non-comparative single arm studies (Baker 2014, Bateman and Roberts 2013, Gentry and Wright 2010, Lientz 2013, Muldoon et al. 2010, Sullivan 2015). Four studies (Baker 2014, Lientz 2013, Sullivan 2015, Muldoon et al. 2010) would have been excluded due to insufficient detail reported about the population.

- Three systematic reviews (Cornish 2017, Huang et al. 2015, National Pressure Ulcer Advisory Panel 2014a). Two (Cornish 2017, National Pressure Ulcer Advisory Panel 2014a) would have been excluded due to an ineligible study design because they were not deemed to be ‘systematic’. One review (Huang et al. 2015) did not report sufficient details about the intervention evaluated in the included studies.

The detailed reasons why the EAC would not have included these studies based on the company’s selection criteria are presented below in Appendix B.

The company's decision to vary the eligible population from the NICE scope was not deemed appropriate. Therefore, the EAC has realigned the selection criteria with the scope. The company's decision to broaden the intervention, however, has remained intact (following a discussion with NICE) but has been made clearer in the updated criteria. Specifically, the eligibility of the intervention has been broadened to include Mepilex Border (general use) when applied to the heel or sacrum, as well as the Mepilex Border Heel and Mepilex Border Sacrum dressings. Due to the sufficient volume of comparative evidence identified, eligible study designs have been limited to RCTs and non-randomised comparative studies. Single arm studies were considered for adverse events only and not clinical effectiveness. The updated EAC criteria are shown in Table 3.1.

Table 3.1: Updated EAC selection criteria

	Inclusion criteria	Exclusion criteria
Population	Patients at risk or at high risk of pressure ulcers in acute care settings	Patients in other care settings (e.g. aged care setting)
Intervention	Mepilex Border Heel dressing, Mepilex Border Sacrum dressing and Mepilex Border dressing (when applied to the heel or sacrum) used as an adjunct to standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers	Other Mepilex dressings
Comparators	Standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers. This may involve a combination of: • Risk assessment with a validated scale • Skin assessment • Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) • Pressure redistribution using devices such as high-specification foam mattress or pressure redistributing cushions. • Other dressings or skin applications to prevent pressure ulcers • Information • Barrier cream (specified situations)	
Outcomes	• Incidence of developing pressure ulcers • Incidence of skin breakdown at the heel and sacrum • Stage of pressure ulcer developed (stage I – IV, unstageable) • Level of patient satisfaction • Additional length of hospital stay as a result of pressure ulcers including ICU and conventional ward bed days. Patient compliance with pressure ulcer prevention strategies • Level of pain and discomfort and impact on quality of life.	

	Inclusion criteria	Exclusion criteria
	• Complications avoided from pressure ulcer prevention e.g. Infection, abscess, septicaemia, bone infections, meningitis. • Ease of use of product • Device related adverse events	
Study design	Randomised controlled trials (RCTs) of any size and duration Prospective and retrospective non-randomised comparative studies will be eligible for inclusion if they report relevant clinical effectiveness or safety data for the relevant intervention and comparator Non comparative or single arm studies will be included for analysis of device-related adverse events only Systematic reviews will be included for reference checking purposes only	News articles, non-systematic reviews, single case reports
Limits	No language restrictions A date limit of 2001 was applied to the search	Studies published before 2001

3.3 Included and excluded studies

The EAC identified 13 studies (reported across 23 records, including protocols and associated abstracts) as eligible for inclusion in the review (see PRISMA diagram in Appendix A and excluded studies table in Appendix C). Of these:

- Four RCTs were included. Three of these were identified and included by the company (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a) and 1 was newly identified by the EAC (Walker et al. 2017) For Kalowes 2016, the EAC identified 4 additional associated records not accounted for by the company (Kalowes et al. 2013b, Kalowes et al. 2012a, Kalowes et al. 2012b, Kalowes et al. 2013a). The EAC identified 2 additional records associated with Santamaria 2015a (Santamaria et al. 2013, Santamaria et al. 2017). Four records were identified by the EAC that are associated with the newly identified Walker 2017 trial (Walker et al. 2017, 2013, Walker and Aitken 2015, Walker et al. 2015).

- Nine comparative observational studies were included (Brindle and Wegelin 2012, Chaiken 2012, Cubit et al. 2013, Haisley et al. 2015, Jin 2018, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Yoshimura et al. 2016). All of these studies were identified and included in the company submission.

All of the studies included by the company were successfully identified by the EAC. However, 22 of these studies were subsequently excluded based on the updated EAC eligibility criteria. This included:

- Two RCTs (Bao and Ji 2010, Santamaria et al. 2015b, Santamaria et al. 2018). Qiuli & Qiongyu 2010 comprised of a single full-text publication reported in Chinese (Bao and Ji 2010). The EAC obtained an English translated version of the paper from the company. On assessment of the English version, the study was excluded as 'ineligible intervention' as there was limited detail on the specific type of Mepilex dressing reported. Santamaria 2018 comprised of an unpublished report obtained from the company and a recently published paper (Santamaria et al. 2015b). However, the trial was excluded because it was conducted in an ineligible setting (i.e. aged not acute care).

- Two seemingly non-randomised comparative observational studies (Koerner 2011, Padula 2017). Padula 2017 reports a budget impact analysis based on a retrospective observational study (Padula 2017). The EAC considered this an ineligible study design and it was, therefore, excluded. Koerner 2011, which comprised a single abstract, was not considered to report sufficient information on the population or intervention to warrant inclusion (Koerner 2011).

- 12 single arm studies. One of the single arm studies (Bateman and Roberts 2013, Gentry and Wright 2010, Walsh et al. 2012) was considered to not report sufficient information about the intervention in the abstract and was, therefore, excluded. 10 single arm studies (Baker 2014, Bateman and Roberts 2013, Brindle 2010, Daukste 2013, Edwards and Lynch 2014, Gentry and Wright 2010, Johnstone and McGown 2013a, Lientz 2013, Muldoon et al. 2010, Sullivan 2015) were excluded as they did not report any device-related adverse event data. One single arm study (NCT02962882), which was newly identified by the EAC, was also excluded for the same reason (2016).

- Seven systematic reviews (Black J et al., Clark et al. 2014, Cornish 2017, Huang et al. 2015, Moore and Webster 2013, National Pressure Ulcer Advisory Panel 2014a, Tayyib and Coyer 2016). Systematic reviews were not deemed an eligible study design by the EAC and were excluded.

Reasons for any disagreement in the company and EAC selections are presented in Table 3.2.

Table 3.2: Comparison of the studies (and associated publications) included in the company review and the EAC review

Study	Associated publications	Included in company review?	Included in EAC review?	Reason for disagreement
Aloweni 2017 (Aloweni et al. 2017)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Baker 2014 (Baker 2014)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Bateman & Roberts 2013 (Bateman and Roberts 2013)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Black 2014 (Black J et al.)	**NA**	**Y**	**N**	Excluded by the EAC as systematic reviews are not an eligible study design.
Brindle 2010 (Brindle 2010)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Brindle & Wegelin 2012 (Brindle and Wegelin 2012)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Chaiken 2012 (Chaiken 2012)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Clark 2014 (Clark et al. 2014)	**NA**	**Y**	**N**	Excluded by the EAC as systematic reviews are not an eligible study design.
Cornish 2017(Cornish 2017)	**NA**	**Y**	**N**	Excluded by the EAC as systematic reviews are not an eligible study design.
Cubit 2013 (Cubit et al. 2013)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Daukste 2014 (Daukste 2013)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Edwards & Lynch 2014	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not

Study	Associated publications	Included in company review?	Included in EAC review?	Reason for disagreement
(Edwards and Lynch 2014)				report any device-related adverse event data
Gentry & Wright 2010 (Gentry and Wright 2010)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Haisley 2015 (Haisley et al. 2015)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Huang 2015 (Huang et al. 2015)	**NA**	**Y**	**N**	Excluded by the EAC as the intervention is not specifically referred to as a "Mepilex" dressing. Limited detail reported.
Jin 2018 (Jin 2018)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Johnstone 2013 (Johnstone and McGown 2013a)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Kalowes 2016 (Kalowes et al. 2016)	(Kalowes et al. 2012a, Kalowes et al. 2013a, Kalowes et al. 2013b, Kalowes et al. 2012b)	**Y**	**Y**	Not applicable. This study was included in both reviews.
Koerner 2011(Koerner 2011)	**NA**	**Y**	**N**	Excluded by the EAC as there is limited detail reported about the intervention and population.
Lientz 2013 (Lientz 2013)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Moore 2013 (Moore and Webster 2013)	**NA**	**Y**	**N**	Excluded by the EAC as systematic reviews are not an eligible study design.
Muldoon 2010 (Muldoon et al. 2010)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
NPUAP 2014 (National Pressure Ulcer Advisory Panel 2014a)	**NA**	**Y**	**N**	Excluded by the EAC as systematic reviews are not an eligible study design.
Padula 2017 (Padula 2017)	**NA**	**Y**	**N**	Excluded by the EAC as ineligible study design.
Park 2014 (Park 2014)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Qiuli and Qiongyu 2010 (Bao and Ji 2010)	**NA**	**Y**	**N**	Excluded by the EAC as there was insufficient detail reported on the type of Mepilex dressing used.

Study	Associated publications	Included in company review?	Included in EAC review?	Reason for disagreement
Richard-Denis 2017 (Richard-Denis et al. 2017a)	(Richard-Denis et al. 2017b) (Gefen and Santamaria 2017)	**Y**	**Y**	Not applicable. This study was included in both reviews.
Santamaria 2018 (Santamaria et al. 2018)	(Santamaria 2015)	**Y**	**N**	Excluded by the EAC as the study setting (aged care) is not eligible.
Santamaria 2015a (Santamaria et al. 2015a)	(Santamaria et al. 2013) (Santamaria et al. 2017)	**Y**	**Y**	Not applicable. This study was included in both reviews.
Santamaria 2015b (Santamaria et al. 2015b)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Sullivan 2015 (Sullivan 2015)	**NA**	**Y**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data
Tayyib 2016 (Tayyib and Coyer 2016)	**NA**	**Y**	**N**	Excluded by the EAC as systematic reviews are not an eligible study design.
Walsh 2012 (Walsh et al. 2012)	**NA**	**Y**	**N**	Excluded by the EAC as the intervention is not specifically referred to as a “Mepilex” dressing. Limited detail reported.
Yoshimura 2016 (Yoshimura et al. 2016)	**NA**	**Y**	**Y**	Not applicable. This study was included in both reviews.
Walker 2017 (Walker et al. 2017)	(2013, Walker and Aitken 2015, Walker et al. 2015)	**N**	**Y**	This study does not seem to have been identified by the company.
NCT02962882 (2016)	**NA**	**N**	**N**	Single arm study. Excluded by the EAC as it does not report any device-related adverse event data

Further details of the included studies identified by the EAC are presented in Table 3.3. Studies reported as conference abstracts or clinical trial records only are highlighted in grey throughout the report. The colour coding in the table relates to whether the study matches the scope fully (green dots), partially (yellow dots) or not at all (red dots).

Table 3.3: Overview of EAC's included studies

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
Comparative studies: Randomized controlled trials						
Aloweni 2017 (Aloweni et al. 2017)	Single-site RCT investigating Mepilex Border Sacrum plus standard care, fatty acids oil spray plus standard care, and standard care (SC) Intervention● Comparator (fatty acids oil spray) ● Comparator (SC) ●	**Patients**: Adult patients recruited within 48 hours of hospital admission. Inclusion criteria specified age ≥21 years, no pre-existing pressure injuries and a high risk (Braden score ≤14) of developing pressure injuries **Mepilex Border Sacrum**: 129 patients **Oil group**:130 patients **SC group**: 202 patients **Setting**: Hospital (medical/surgical wards); Singapore **Funding:** SingHealth Foundation ●	Pressure ulcers assessed according to NPUAP/EPUAP (2014) with any event ≥ stage I pressure ulcer reported. Sacra assessed by a registered nurse at least once daily and a study investigator assessed patients every 3 days. Patients followed-up every 3 days up to 14 days of hospital stay Mean duration of Santamaria stay was 6.7 days (SD ±4.3)	Incidence rate of any stage I pressure injury (NPUAP/EPUAP 2014). Subgroup analysis by Braden score (≤12, ≥13) ●	**Mepilex Border Sacrum**: 29 withdrawals (sacral excoriation, diarrhoea, dying/death, treatment contamination, withdrawal requested) **Oil group**: 18 withdrawals (sacral excoriation, dying/death, ICU admission, treatment contamination, withdrawal requested) **SC group**: 17 withdrawals(sacral excoriation, diarrhoea,	Authors conclude that additional preventive measures seem clinically beneficial in reducing sacral pressure injuries in the general ward acute care setting Limitations reported by the authors included single-site study, only recruited patients who were high-risk on admission, and study was slightly under-powered Fatty acids oil spray is out of scope Study matches scope and provides limited non-UK comparative data

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
					operation >4 hours, dying/death = 9, treatment contamination of treatment, withdrawal requested)	
Kalowes 2016 (Kalowes et al. 2016)	Single-site RCT comparing Mepilex Border Sacrum plus standard care with standard care alone (based on SKIN bundle) Intervention● Comparator ●	**Patients**: Patients were adults (≥18 years) admitted to cardiac, medical, surgical and trauma ICUs with a Braden score ≤13, and intact sacral skin. Patients were excluded if they existing sacral pressure ulcers, moisture-related skin damage on admission, and/or or were receiving end-of-life care or undergoing withdrawal of life-sustaining treatments. Overall, 366 patients with a mean age of 65.9 years and mean Braden score of 11.9 **Mepilex Border Sacrum**: 184 patients; 103 (56.0%) male **Standard care**: 182 patients; 100 (54.9%) male **Setting**: Level II trauma hospital; USA **Funding:** None reported ('Financial disclosures') ●	Daily skin assessment by a member of the research team, with pressure ulcers staged according to NPUAP (2014). Pressure ulcer outcome data for patients transferred to medical/surgical units, (dressing removed) were tracked during the hospital stay via the electronic medical record. Patients were followed-up within 24 hours of admission to the ICU throughout their ICU stay, and for 6 months following discharge	Incidence, stage (NPUAP 2014) and location of pressure ulcers, number of pressure ulcers per patient, length of stay, mortality, and costs. Adverse events also reported (not explicitly monitored) ●	**Mepilex Border Sacrum:** 31 deaths **Standard care:** 36 deaths	Based on the study findings, the hospital has mandated the prophylactic use of Mepilex Border Sacrum foam dressings for all patients who are at high risk for pressure ulceration in all care areas, including procedural and operating rooms Limitations reported were the single-site vs multisite design, results not generalizable to other populations, and the nature of the treatment meant there is a risk of bias due to a lack of blinding

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
			Median LOS was 7.0 days (IQR: 4-13) in the ICU and 14.0 days (IQR: 8-25) in the hospital			Study matches scope and provides limited non-UK comparative data
Santamaria 2015a (Santamaria et al. 2015a) (BORDER)	Single-site, open-label RCT comparing standard care plus Mepilex Border Sacrum and Mepilex Heel with Tubifast retention bandage to standard care Intervention (Sacrum) ● Intervention (Heel) ● Comparator ●	**Patients:** Patients aged >18 years who were admitted to the ED and ICU for critical illness and/or major trauma, and had no suspected or actual spinal injury precluding the patient being turned, pre-existing sacral or heel pressure ulcer, trauma to sacrum and/or heels **Mepilex Border Sacrum/ Mepilex Heel**: 219 patients; mean age 54 (SD 20.8) years; male/female: 126/89 **Standard care**: 221 patients; mean age 56 (SD 20.5) years; male/female 132/82 **Setting**: Hospital Trauma Centre (mixed medical/surgical ICU); Australia **Funding:** Not reported ●	Patients were reviewed every 24 hours for the duration of their ICU stay. Pressure ulcers were defined according to the 4-point staging system of the AWMA (2001)** Follow-up was until discharge from ICU. Mean duration of ICU stay was 91 (SD 112) hours in Mepilex group and 86 (SD 101) hours in the standard care group	Incidence rate of pressure ulcers in the ICU (AWMA 2001), by cases and anatomical site. Adverse events were not a pre-specified outcome but were discussed ●	**Mepilex Border Sacrum/ Mepilex Heel**: 3 deaths in ED, 17 lost to follow-up/not for ICU/transferred, and 38 transferred from ICU prior to first pressure ulcer assessment **Standard care:** 1 death in ED, 29 lost to follow-up/not for ICU/transferred, 39 discharged from ICU prior to first pressure ulcer assessment	Single-site study Authors commented that it was not possible to determine whether the success of the intervention was due solely to dressing use being commenced in the ED. Study out of scope with respect to heel application: the Mepilex Heel product (3-layer non-adhesive dressing) uses a different technology to Mepilex Border (5-layer, self-adhesive dressing) Study matches scope for sacrum application only (Mepilex Border Sacrum), and provides limited non-

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
						UK comparative data on 1 outcome Trial registered as NCT01356459
Walker 2017 (Walker et al. 2017)	Single-site, parallel-group, pilot RCT comparing Mepilex Border Sacrum plus standard care with standard care Intervention● Comparator ●	**Patients:** Patients admitted to surgical care unit and ED, or participating medical and orthopaedic surgical wards, who were aged ≥18 years, and at high risk or greater of pressure injury (Waterloo risk score15+) on hospital admission. Exclusion criteria: suspected or actual spinal injury that prevented repositioning, lower back surgery (lumbar spine) that prevented sacral dressing application, existing sacral pressure injury, sacral injury/allergy at hospital admission, faecal incontinence, or need for interpreter present. Overall, median age 75 years (IQR 49-91) and 70% female **Mepilex Border Sacrum**: 39 patients; female/male: 23 (59%)/16 (41%) **Standard care**: 38 patients; female/male: 31 (82%)/7 (18%)	Baseline high-resolution digital photograph of sacral area. Sacral skin integrity and/or dressing assessment at least once daily, with high-resolution digital photos taken every third day. Assessment of photos guided by the NPUAP/EPUAP pressure injury and staging classification system (reported by AWMA 2012) Study duration 5 months. Follow-up duration not explicitly reported but likely on discharge from ward. Median time (days) the dressings remained in situ was 2 (IQR: 1-3).	Feasibility criteria, incidence and severity of pressure injury based on digital photos (NPUAP/EPUAP). Patient comfort (self-assessment) and costs were not pre-specified outcomes but were reported ●	3 patients allocated to the dressing were excluded (2 for protocol violations and 1 consent withdrawal). 5 patients in each group without outcome assessment due to early discharge from ward, dressing could not be applied (lumbar spinal block or spinal surgery), or patient removed dressing due to discomfort	Over 70% of the overall population were female, with significantly higher proportion of females in the comparator group Limitations reported by the authors included lack of generalizability to other settings (single-site pilot study with small sample size), participant attrition, and protocol inconsistency due to disparity in body weight assessment and probably mattress variation. At the time of the study, the larger size dressing was unavailable for patients assessed as obese

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
		Setting: Tertiary health facility (surgical care, ED, participating medical/surgical wards); Australia **Funding**: National Health and Medical Research Council's Centre of Research Excellence in Nursing; Centre from Health Practice Innovation, Griffith University ●	Median time (hours) from recruitment to discharge **Mepilex Border Sacrum**: 121 (IQR 73-171) **Standard care:** 122 (IQR 88-198)			Authors noted that blinding of the outcome assessor was considered a challenge as the dressing left atraumatic skin marks; use of a sham dressing (if approved) may have left similar markings Trial registered as ACTRN12613001328763 Study matches scope and provides limited non-UK comparative data
Comparative studies: Observational trials						
Brindle & Wegelin 2012 (Brindle and Wegelin 2012)	Single-site prospective study comparing standard care plus Mepilex Border Sacrum with standard care Intervention●	**Patients**: High-risk patients in a cardiac surgery ICU. Patients (≥18 years) enrolled if they had: a surgical procedure >6 hours (may be cumulative surgeries = 6 hours); cardiac arrest this admission; vasopressors >48 hours; in shock, SIRS, MODS; or if they had 5 or more of the pre-specified conditions; and had no existing pressure ulcer	Skin assessments conducted daily and patients followed up using a tracking form. Any suspected skin breakdown occurring around the sacrum, coccyx, or gluteal fold was immediately reported. The final	Incidence of any stage of pressure (scale not stated), hours in the ICU and pressure-ulcer-free survival. ●	No data collection forms for 5 patients; group assignment was not known. **Mepilex Border**	No statistically significant difference in pressure ulcer incidence between the 2 groups, but pressure ulcer incidence was lower than anticipated over the study period for both groups, possibly because the

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
	Comparator ●	on admission >stage I (scale not stated). Mean age was 61.8 years (SD ±13.2), 65.9% were male, and mean Braden Scale risk score was 11.2 (SD ±2.12). **Mepilex Border Sacrum**: 56 patients **Standard care group**: 39 patients **Setting**: Cardiac surgery ICU; USA **Funding:** Authors declared no conflicts of interest ●	skin evaluation was on the day of discharge. Patients were followed-up until they left the ICU or were removed from study if they expired/left ICU before 48 hours from admission.		**Sacrum**: 6 drop-outs **Standard care group**: 4 drop-outs.	intervention dressing was applied to all patients in the operating room as part of their standard interventions Small sample size The original trial was a multicentre design; withdrawal of 2 of the 3 sites reduced the power of the study to detect differences between groups Study matches scope and provides limited non-UK comparative data
Chaiken 2012 (Chaiken 2012)	Single-site non-experimental prospective study comparing Mepilex Border Sacrum plus standard care with retrospective comparison	**Patients:** All patients admitted during the observation period without any ulcers (stage not specified) received the intervention group (Mepilex Border Sacrum) Comparator group comprised patients for whom sacral hospital-acquired pressure ulcers had been monitored over an initial baseline period and who had no ulcers (stage not specified).	**Mepilex Border Sacrum:** Prospective observation over 6 months with skin assessments every 24 hours and wound care nurse notified of any skin alterations **Standard care**: Retrospective baseline data over a 35-month period from	Sacral HAPU incidence in the intervention group and sacral HAPU prevalence in the comparator group Costs were not a pre-	Loss to follow-up not reported	Prospective study with retrospective control; unclear whether any patients studied during the baseline period continued into the prospective study Authors commented that they were unable to directly compare

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
	period of standard care Intervention● Comparator ●	Participants had a mean age of 65.0 years (range: 17-105) **Mepilex Border Sacrum**: 273 patients. **Standard care:** 291 patients **Setting**: Level 2 trauma hospital (ICU); USA **Funding:** Authors stated that no financial assistance was obtained for the study ●	monthly skin assessments based on NDNQI procedure and verified by a WOC nurse	specified outcome measure but some were reported. ●		results using inferential statistics as they initially measured sacral HAPU based on NDNQI procedures, as compared with measuring HAPU incidence Study partially matches scope. Reported total cost of dressings but not UK-based
Cubit 2013 (Cubit et al. 2013)	Single site pilot study, with a non-randomised 1 sample experimental design, comparing Mepilex Border Sacrum plus standard care (prevention plan) with a control group who had received a management plan (use of	**Patients**: Male and female patients admitted via the ED, who were aged ≥65 years of age and presented with a medical condition, assessed to be 'at high risk' or 'very high risk' for developing a pressure injury according to the Waterlow Pressure Ulcer Risk Assessment Tool, and who did not have an existing sacral pressure injury. **Mepilex Border Sacrum**: 51 invited patients. Mean age was 82.0 years (SD=8.3; range 65-96); 37.3%male **Control group**: 58 patients who weren't asked to participate. Mean age 82.0 years (SD = 8.3; range 65-95); 46.5% male	Skin assessment every 8 hours, with any change in the patient's skin integrity reviewed by the Wound Management Clinical Nurse Consultant and an appropriate management implemented and recorded. Pressure injuries graded using 4-stage system approved by the AWMA. Patients followed-up for duration of	**Mepilex Border Sacrum:** Presence and stage of sacral pressure injuries (AMWA 4-stage system) **Control group**: Pressure injury (retrospective data)	**Mepilex Border Sacrum:** Not reported **Control group:** N/A (retrospective review)	Single-site study Small sample of patients aged ≥65 years Authors concluded that application of a low shear dressing with a soft silicone contact layer may prevent pressure injury in older 'at high risk' medical patients, and should be considered as part of a prevention strategy initiated in the ED

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
	prevention measures not documented) Prospective intervention group. Retrospective data collection for control group Intervention: ● Comparator: ●	**Setting**: Hospital (3 medical wards); Australia **Funding:** Practice Development grant (source unclear); Mölnlycke Health Care provided financial support to present study findings at conferences ●	hospital stay or until end of trial.	●		Reported limitations included the small sample size and restriction to older aged patients, and that it was not documented whether the control group had received any preventive measures Mölnlycke Health Care provided the dressings and financial support to present study findings at conferences Study partially matches scope and provides limited non-UK comparative data
Jin 2018, unpublished (Jin 2018)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
	[redacted]	[redacted]	[redacted]			[redacted]
Haisley 2015 (Haisley et al. 2015)	Single-site pilot cohort study comparing Mepilex Border Heel to both heels plus standard care (pressure ulcer prevention measures) with standard care (retrospective control) Intervention: ● Comparator: ●	**Patients**: Patients admitted to the coronary care unit and cardiovascular ICU who were non-ambulant or at high risk for heel pressure ulcers (conditions such as diabetes mellitus, peripheral vascular disease, poor nutritional status, constant heel friction) and had no pre-existing heel pressure ulcers or pre-existing trauma to heels. **Mepilex Border Heel**: 31 patients. **Control group**: Number of patients not reported **Setting**: coronary care/ cardiovascular ICU; USA	Dressings were lifted daily to check skin integrity and reapplied as needed. Patient's heels were checked for signs and symptoms of pressure ulcer development prior to discharge from ward Patients followed up until discharge	Pressure ulcer incidence (staging method not stated). Trial extended for 3 months to validate the outcome ●	Not reported.	Poster only – limited information Single-site study Number of patients in the control group not reported Based on the results of this small sized study, the facility intends to incorporate this dressing into its skin care/wound care protocol Study partially matches scope but

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
		Funding: Mölnlycke Health Care provided poster support (unclear whether this was financial) ●				provides limited data for 1 outcome in non-UK setting Mölnlycke Health Care provided poster support
Park 2014 (Park 2014)	Single-site, non-randomised comparison cohort (quasi-experimental) study comparing Mepilex Border plus standard care with standard care (standard pressure ulcer preventive care regimen) Intervention ● Comparator ●	**Patients**: Patients aged ≥40 years who were admitted to the ICU. Patients with a Braden Scale score ≤16 and no pressure ulcers or incontinence-associated dermatitis were included in the study. Overall, 64% male with mean age 64 (SD11) years and more than half aged ≥65 years, and a mean Braden Scale score of 12.7 (SD 2.0) **Mepilex Border**: 52 patients, 37 (71%) male **Standard care**: 50 patients, 28 (56%) male **Setting**: Medical centre (2 ICUs); South Korea **Funding:** Authors declared no conflicts of interest ●	Dressings were changed every 3 days or more often if soiled or displaced. Skin assessments, including staging (according to NPUAP 2009) and presence of pressure ulcers and IAD, were performed by 2 wound care nurses during patient rounds every 3 days for the duration of the study. Study duration was 9 days.	Incidence and stage of pressure ulcer occurrence (NPUAP 2009), and severity of IAD ●	No loss to follow-up	Patients aged ≥40 years, and higher proportion of males in the intervention group Single-site study Small sample size Study matches scope and provides non-UK comparative data for a limited number of outcomes
Richard-Denis 2017 (Richard-Denis et al. 2017a)	Single-site retrospective study conducted on a prospective	**Patients:** Patients admitted to a level-I trauma centre following traumatic spinal cord injuries. Inclusion criteria specified patients with spine trauma that involved a	Skin assessment every 8 hours in dressing group but unclear timing of assessments in gel	Occurrence and severity of sacral pressure ulcer during	N/A (retrospective study)	Retrospective study with the 2 interventions studied over consecutive time

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
	cohort over 2 consecutive time periods. The study compared pre-operative use of Mepilex Border Sacrum with gel mattress, both in conjunction with basic pressure ulcer prevention protocol Intervention● Comparator ●	spinal cord injury above the L1-L2 intervertebral disc and had surgery performed in the study institution **Mepilex Border Sacrum**: (post 1 Oct 2014): 89 patients; mean age 50.7 (SD 18.3) years, 73.0% male **Gel mattress group** (pre 1 Oct 2014): 286 patients; mean age 47.8 (SD19.4), 81.0% male **Setting**: Level 1 SCI-specialised trauma centre; Canada **Funding:** US Army, Medical Research and Material Command ●	mattress group. Skin evaluation was collected in a routine data sheet assessing evaluation, observation and treatment. Pressure ulcer development and staging was based on clinical practice guidelines (NPUAP 2007) Follow-up was until discharge from acute care. The average acute care LOS was approximately 1 month in both groups.	acute hospitalisation (NPUAP 2007) ●		periods at a single site The groups were imbalanced in terms of patient numbers: 286 (gel mattress) vs 89 (dressing) Patients in the dressing group had gel pads placed to replace the use of a mattress as part of standard care The authors noted that the delay for PU appearance was not available, which would have helped in evaluating the efficacy of the preventive dressing during the pre-operative period Study partially matches scope and provides comparative data in a select

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
						population (spinal trauma injuries)
Santamaria 2015b (Santamaria et al. 2015b) (BORDER II)	Single-site prospective cohort study with retrospective control group from the Border I trial. The study compared standard care plus Mepilex Border Heel with Tubifast retention bandage to standard care Intervention● Comparator ●	**Patients:** All major trauma and critically ill patients aged ≥18 years who were admitted to the ED then transferred to ICU, and had no pre-existing heel pressure ulcer, trauma to the heels, or spinal injuries which precluded repositioning **Mepilex Border Heel**:191 patients; mean age 55 (SD 19.7) years; male/female (missing cases): 123/67 (1) **Control group** (Border I trial): 221 patients; mean age 56 (SD 20.5) years; male/female (missing cases): 132/82 (7) **Setting**: Hospital ICU; Australia **Funding:** Unrestricted research grant from Mölnlycke Health care AB ●	Skin and dressings were checked daily until patients were ambulant or left the ICU. Pressure ulcers were identified and categorised (4-point system for categories I to IV) based on AWMA definitions. Follow-up was until discharge from ICU. Mean duration of ICU stay was 107 (SD 123) hours in Mepilex group and 86 (SD 101) hours in control group	Incidence rate of pressure ulcers in the ICU (AWMA 2001). Usability of the dressing was not a pre-specified outcome but was discussed ●	**Mepilex Border Heel**: 1 death in ED, 16 discharged from ICU prior to assessment, 24 lost to follow-up/not for ICU/transferred **Control group** (Border I trial): 1 death in ED, 39 discharged from ICU prior to assessment, 29 lost to follow-up/not for ICU/transferred	Prospective study with retrospective control (Border I trial) conducted over different time periods Single-site study The authors acknowledged the disparity in ICU between the 2 groups as a limitation of the study, but considered it would not favour the dressing as the prolonged stay could increase the risk of pressure ulcer development The study was funded through an unrestricted research grant from Mölnlycke Health Care Study matches scope and provides limited

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments
						comparative data in a non-UK setting
Yoshimura 2016 (Yoshimura et al. 2016) (BOSS trial)	Multisite, prospective, dual-centre, open-label, split-body comparison sham study of Mepilex Border and polyurethane film dressings, in conjunction with the standard positioning protocol Intervention● Comparator ●	**Patients:** Eligible patients were aged ≥20 years and were undergoing elective spinal surgery in the prone position using a Relton-Hall frame. Eligibility criteria also specified the exclusion of patients undergoing emergency surgery, presence of skin disorders or scars in the area to be observed, and remarkable spondylosis deformation. 100 eligible patients underwent bilateral comparison of the 2 dressings, applied to the chest and iliac crest, for the duration of surgery. The mean age of the patients was 64.6(SD 15.6) years, 67 (67.0%) were male, and the mean procedure duration was 2.6 (SD 1.2) hours. **Setting**: Two hospital operating rooms; Japan **Funding:** Authors declared no conflicts of interest ●	Operating room nurses checked for intraoperative pressure ulcers 30 minutes after the surgery was completed and the patient was back in the supine position. Pressure ulcers were categorized according to NPUAP 2014. All patients were followed-up for any new pressure ulcers by review of the medical records. Duration of follow-up was not stated but patients who developed a pressure ulcer or DTI within 1 week after surgery were classified as having intraoperative pressure ulcers.	Incidence rate of intraoperative pressure ulcers at the chest and iliac crest, difference in the incidence rates between dressings for patients with/without intraoperative pressure ulcers ●	No loss to follow-up	Bilateral comparison study of 2 types of dressing, applied to chest and iliac crest in the same patient after the induction of anaesthesia. Few results reported according to dressing location. For both types of dressing, pressure ulcers only developed at chest sites Results not generalizable to other institutions and use of dressings in other surgical positions and with other surgical procedures Study matches scope but reports little relevant data Trial registered as UMIN000021696

Study name (acronym)	Design and intervention(s)	Participants* and setting	Follow-up	Outcomes	Withdrawals	Comments

* Age and gender was not consistently reported in the studies. Where data were reported, details of age and gender have been included.
** The staging system recommended in AMWA (2001) is consistent with NPUAP (2014) (Murray LD et al. 2001).

Grey shading indicates that the paper is available as an abstract/poster only.
Yellow shading reflects information submitted under 'academic in confidence' and corresponding EAC comments on this study.

Colour coding relates to whether the study matches the scope fully, partially, or not at all: ●●●

Abbreviations: AMWA, Australian Wound Management Association; DTI, deep tissue injury; ED, emergency department; EPUAP, European Pressure Ulcer Advisory Committee; HAPU, hospital-acquired pressure ulcer; IAD, incontinence-associated dermatitis; ICU, intensive care unit; IQR, interquartile range; LOS, length of stay; MODS, multiple organ dysfunction syndrome; NDNQI, National Database of Nursing Quality Indicators; NPUAP, National Pressure Ulcer Advisory Association; OPCABG, off-pump coronary artery bypass graft; SD, standard deviation; SIRS, systemic inflammatory response syndrome; WOC, wound, ostomy and continence.

3.4 Overview of methodologies of all included studies

The company reported the methodologies of the included studies in Section 7.4.1 of its submission. Of the 4 randomised controlled trials (RCTs) included by the EAC, 3 were RCTs included in the company submission (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a). Tables B5.1, B5.2, B5.4, Submission). The fourth RCT (Walker et al. 2017) was a new study identified by the EAC search. The 9 comparative observational studies (Brindle 2010, Chaiken 2012, Cubit et al. 2013, Jin 2018, Haisley et al. 2015, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Yoshimura et al. 2016) included by the EAC were all included in the company submission (Tables B6, Submission). No single-arm studies with adverse events relevant to the scope were identified by the EAC.

The EAC has reviewed the tables and did not find any major discrepancies in the information presented and that reported in the published literature. The studies were generally not well reported in the published literature and descriptions of their methodology were often unclear, particularly in relation to the interventions and control treatments.

The EAC has extracted further information on these studies as required and summarised the methodologies of all included studies, including the new study identified by the EAC, in Table 3.3. This report focuses in particular on comparative evidence from the RCTs, as the RCT is generally considered to be the most appropriate study design for evaluating the effects of an intervention (Centre for Reviews and Dissemination 2009).

Evidence from RCTs included by the EAC

The 4 included RCTs were all published as full papers and compared Mepilex Border Sacrum plus standard care with standard care alone. One RCT also evaluated fatty acids oil spray plus standard care versus standard care (Aloweni et al. 2017) and another also evaluated the addition of Mepilex Heel to standard care (Santamaria et al. 2015a). Mepilex Heel is a 3-layer non-adhesive dressing which requires fixing in place, whilst Mepilex Border Heel is a 5-layer self-adhesive dressing. Fatty acids oil spray and Mepilex Heel are both interventions outside of the scope.

Standard care varied across the RCTs but specific components that were aligned with the scope included pressure redistribution in 4 RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a, Walker et al. 2017), both regular repositioning and skin care in 2 RCTs (Aloweni et al. 2017, Kalowes et al. 2016), and skin assessment (Walker et al. 2017) and risk assessment by Braden score (Santamaria et al. 2015a) in 1 RCT each.

The studies ranged in overall size from 77 participants (Walker et al. 2017) to 461 participants (Aloweni et al. 2017), with numbers of patients fairly well-balanced across the treatment arms. The exception was the trial reported by Aloweni et al. (Aloweni et al. 2017), in which the authors stated that the participants were randomized in a 1:1:2 ratio across treatments arms, but the standard care alone arm (n=202) was not twice the size of the Mepilex Border Sacrum arm (n=129).

The populations in all 4 studies were well-matched with the scope of the decision problem, recruiting adult patients at high-risk of pressure ulcers in intensive care units, medical/surgical wards and emergency departments. One study recruited patients with a Braden scale risk score ≤14 (Aloweni et al. 2017), 1 with a Braden score ≤13 (Kalowes et al. 2016) and 1 with a Waterloo risk score of 15+ (Walker et al. 2017); the fourth study (Santamaria et al. 2015a) did not specify the level of risk as part of their eligibility criteria, but both intervention and control group patients had a mean Braden score of 12. Details of patient characteristics were poorly reported across the studies. One study reported a mean age of patients of 65.9 years (Kalowes et al. 2016), 1 reported a median age of 75 years (Walker et al. 2017), 1 reported mean ages of 54 and 56 years in the intervention and control groups, respectively (Santamaria et al. 2015a), and 1 did not reported the number of patients according to age ranges (Aloweni et al. 2017). Two studies reported slightly higher proportions of males of approximately 40% to 55% in individual treatment arms (Santamaria et al. 2015a) (Kalowes et al. 2016). In a further study (Walker et al. 2017), over 70% of the overall population was female but with a significantly higher proportion of females in the comparator group compared with the intervention group (82% vs 59%, p=0.03). The authors reported that randomization involved a stratified approach to ensure even distribution of participants' diagnostic category (medical and surgical) but did not describe the actual variables stratification was based on.

The studies reported few outcomes. The most commonly reported were the incidence rate and severity of pressure ulcers, as assessed using established guidelines (NPUAP/EPUAP 2014 or unspecified; AWMA 2001). None of the studies pre-specified adverse events as an outcome in their methodology. Follow-up was typically until discharge.

All but 1 study (Walker et al. 2017) reported conducting power calculations to ensure that the study was adequately powered. Walker et al. (Walker et al. 2017) did not explicitly report conducting a power calculation in their published protocol (2013). The authors acknowledged that the number of patients recruited would be insufficient to statistically determine an effect but considered it suitable for the main objective of their pilot study: to determine the feasibility and effect size to inform a larger RCT.

All 4 studies were conducted outside of the UK in Australia (Santamaria et al. 2015a, Walker et al. 2017), Singapore (Aloweni et al. 2017) and the USA (Kalowes et al. 2016). Three of the studies reported on their funding status and stated the source of their funding or declared no financial disclosures (Aloweni et al. 2017, Kalowes et al. 2016, Walker et al. 2017). The remaining study did not report any information on the funding status (Santamaria et al. 2015a).

Evidence from comparative observational studies included by the EAC

Nine comparative observational studies were included. Seven studies were published as full papers (Brindle and Wegelin 2012, Chaiken 2012, Cubit et al. 2013, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Yoshimura et al. 2016), and 1 was only available as a conference poster (Haisley et al. 2015). There was also 1 unpublished study report (Jin 2018) obtained from the company.

Seven studies compared the intervention plus standard care versus standard care alone:

- Studies of Mepilex Border Sacrum (Brindle and Wegelin 2012, Chaiken 2012, Cubit et al. 2013, Richard-Denis et al. 2017a).
- Studies of Mepilex Border Heel (Haisley et al. 2015, Santamaria et al. 2015a).
- 1 study of Mepilex Border (Park 2014).

One of these studies (Richard-Denis et al. 2017a) specifically focused on the gel mattress component of the standard care in use.

Of the remaining 2 studies, 1 (Jin 2018) compared [redacted] The other (Yoshimura et al. 2016) conducted a bilateral comparison of Mepilex Border and Opsite flexifix polyurethane film dressing applied to the chest and heel; application to the chest site is outside of the scope. There was a wide variation in standard care across the studies, with the majority utilising a mixture of components aligned with the scope. One study (Haisley et al. 2015), published as a conference poster only, specified the use of standard pressure ulcer prevention measures but did not describe any individual components, and the unpublished study report (Jin 2018) provided no further details on standard care. In a further study (Yoshimura et al. 2016) it was unclear as a standard positioning protocol was used to hold the patient in the required surgical position, with foam mattress pads used to redistribute the pressure exerted by the Relton-Hall frame.

The studies ranged in size from 31 patients in the Mepilex Border Heel group (number in comparator group not reported (Haisley et al. 2015) to an overall size of 564 (Chaiken 2012), with a fairly equal distribution of patients between the 2 treatment arms. There were 2 exceptions (Yoshimura et al. 2016, Richard-Denis et al. 2017a). Yoshimura et al. (Yoshimura et al. 2016) conducted a bilateral comparison in which 100 patients each received both Mepilex Border and Opsite flexifix, to opposite sides of the body. In Richard-Denis et al. (Richard-Denis et al. 2017a), patients were followed over 2 different time periods according to the prevention protocol in use at time of admission to the emergency department: patients were transferred onto a gel mattress prior to 1 Oct 2014 (n=286) and after this date received the Mepilex Border Sacrum dressing (n=89).

The studies generally matched the scope of the decision problem in terms of their populations, recruiting patients at risk or high risk of pressure ulcers in acute care settings, predominantly on admission to emergency departments, trauma centres, ICUs and cardiac surgery. [redacted], 1 study specifically recruited patients admitted following traumatic spinal cord injury with a spine trauma above the L1-L2 intervertebral disc and who had surgery performed in the study institution (Richard-Denis et al. 2017a), and 1 study included only patients undergoing elective spinal surgery in the prone position using a Relton-Hall frame (Yoshimura et al. 2016).

Details of patient characteristics were poorly reported across the studies. Mean age, where reported, ranged from 47.8 and 50.7 years (Richard-Denis et al. 2017a) to [redacted] in general adult populations, and was 64 years in 1 study (Park 2014) conducted in patients aged ≥40 years and 82.0 years in a further study (Cubit et al. 2013) of patients aged ≥65 years. One study did not report age (Haisley et al. 2015). Study populations comprised a higher proportion of males in 6 studies (Brindle and Wegelin 2012, Jin 2018, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Yoshimura et al. 2016), a slightly higher proportion of females in 1 study (Cubit et al. 2013); and was not reported in the remaining 2 studies (Chaiken 2012, Haisley et al. 2015).

The studies reported few outcomes. The most commonly reported outcomes were the incidence rate and stage of pressure ulcers, based on established guidelines (AWMA 2001 or unspecified; NPUAP 2014; NPUAP 2009; NPUAP 2007). Two studies (Brindle and Wegelin 2012, Haisley et al. 2015) did not report using a validated scale for the assessment. One prospective study (Chaiken 2012) reported incidence for patients receiving Mepilex Border Sacrum (unclear assessment method) but prevalence (established based on NDNQI procedure) for the retrospective control (standard care). Two studies

specifically measured the incidence of intraoperative pressure ulcers (Jin 2018, Yoshimura et al. 2016). None of the studies pre-specified adverse events as an outcome in their methodology. Follow-up was typically until discharge/transfer from the unit or ward, or discharge from the hospital.

Only 3 studies reported conducting power calculations (Jin 2018, Park 2014, Santamaria et al. 2015b) prior to study initiation, with a further study (Brindle and Wegelin 2012) stating that the power of their study had been reduced following a change in study design and the withdrawal of 2 of the 3 study sites. There were 2 prospective studies (Brindle and Wegelin 2012, Jin 2018), 5 prospective studies with a retrospective control group (Cubit et al. 2013, Haisley et al. 2015, Santamaria et al. 2015b, Yoshimura et al. 2016) or comparison period (Chaiken 2012) and 1 retrospective study based on prospective data collection (Richard-Denis et al. 2017a). One study did not report whether patients were recruited prospectively or retrospectively (Park 2014).

All 9 studies were conducted outside of the UK: 3 in the USA (Brindle and Wegelin 2012, Chaiken 2012, Haisley et al. 2015), 2 each in Australia (Cubit et al. 2013, Santamaria et al. 2015a) and South Korea (Jin 2018, Park 2014) and 1 each in Canada (Richard-Denis et al. 2017a) and Japan (Yoshimura et al. 2016). Of the 8 studies reporting on their funding status, 3 studies (Cubit et al. 2013, Haisley et al. 2015, Santamaria et al. 2015b) stated they received financial assistance or other support from Mölnlycke Health Care AB (the company), 1 received funding from the US Army (Richard-Denis et al. 2017a), and 4 declared no financial disclosures or conflicts of interest (Brindle and Wegelin 2012, Chaiken 2012, Park 2014, Yoshimura et al. 2016). [redacted].

3.5 Overview and critique of company's critical appraisal

3.5.1 Critique of the company's critical appraisal

The company critically appraised its included studies using separate tools for the RCTs and comparative observational studies. The RCTs were assessed using criteria proposed by the Centre for Reviews and Dissemination (Centre for Reviews and Dissemination 2009), which rates the appropriateness of sequence generation (i.e. randomization), allocation concealment, patient groups, blinding of patients and personnel, study withdrawals/drop-outs, selective reporting, and data analysis and incomplete data, based on 7 questions, which require a yes/no/not clear/not applicable response.

The comparative observational studies were appraised using an adaptation of the Critical Appraisal Skills Programme's checklist for cohort studies (Critical Appraisal Skills Programme). The 7 questions, which all required a yes/no/not clear/not applicable response, addressed aspects relating to cohort

recruitment, measurement of exposure, measurement of outcome, identification and accounting for confounding factors, patient follow up, and precision of the results. The tools used were appropriate to the study designs.

The company did not explain how some of the questions had been applied (e.g. the difference between measurement of the exposure and measurement of the outcome) or provide justifications of how the ratings for each were assigned. Based on the company's ratings (Tables B7 and B8, Submission), all of the included studies met the majority of criteria adequately or were not clear, although there was a slight tendency towards the more positive rating when data were likely insufficient. There were also some inconsistencies in the interpretation of some criteria, for example, allocation concealment in RCTs, and the overall rating for 'precision' in observational studies had not always been assigned. The company did not attempt to summarise the findings of the critical appraisal, and they made little reference to it in the qualitative review of the results. However, the company noted that the appearance of the dressings made blinding impossible in all of the studies presented in the submission.

3.5.2 EAC's critical appraisal

The EAC undertook its own critical appraisal for all included studies based on the same appraisal tool and checklist used in the company submission, i.e. criteria proposed by the Centre for Reviews and Dissemination for the RCTs and CASP checklist for cohort studies (CASP) for the comparative observational studies (Centre for Reviews and Dissemination 2009) (CASP UK 2013).

A summary of the critical appraisal focusing on the internal and external validity of the studies in relation to the decision problem is presented in Table 3.4 while the detailed completed checklists for both study designs are provided in Appendices D and E. For RCTs, to determine whether a study adequately addressed the criteria (i.e. yes, no or not clear), guidance from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins (2011)) was used to apply a judgement. For observational studies, the EAC has provided explanatory notes for key questions in the checklist at the bottom of the corresponding detailed appraisal table (Appendix E).

Four RCTs and 9 comparative observational trials have been critically appraised by the EAC. The critical appraisal focuses on RCTs because, if conducted well, they offer the potential for a lower risk of bias.

Table 3.4: Summary of critical appraisal in relation to decision problem

Study	Internal validity[1]	External validity[2]
Randomized controlled trials		
Aloweni 2017 (Aloweni et al. 2017)	**Acceptable** Sequence generation, allocation concealment, and outcome measurement/reporting were acceptable. Patients and investigators not blinded given nature of treatments; outcome assessors not blinded. Groups similar in prognostic factors. Imbalances in drop-outs. ITT analysis but unclear how missing data handled.	**Acceptable** Patients (high-risk; medical/surgical wards) and intervention in line with scope. Relevant for 1 outcome reported in the scope: incidence of any stage I pressure injury. Subgroup analysis conducted by risk of pressure ulcer (Braden score). Eligible comparator (standard care alone). Relevant for use of some standard care components reported in scope, including frequent repositioning, pressure redistribution, and skin care. Non-UK setting (Singapore)
Kalowes 2016 (Kalowes et al. 2016)	**High** Sequence generation, allocation concealment, and outcome measurement/reporting were acceptable. Patients and investigators not blinded given nature of treatments; outcome assessors not blinded. Groups similar in prognostic factors and drop-outs. ITT analysis but unclear how missing data handled.	**Acceptable** Patients (high-risk; ICUs) and intervention in line with scope. Relevant for some outcomes reported in the scope, including pressure ulcer incidence and stage, and AEs. Eligible comparator (standard care - SKIN bundle). Relevant for use of some standard care components reported in scope, including regular repositioning, pressure redistribution, and skin care. Non-UK setting (USA)
Santamaria 2015a (Santamaria et al. 2015a)	**Acceptable** Sequence generation was acceptable but allocation concealment unclear. Study not blinded (described as open-label trial). Groups similar in prognostic factors. Unclear/limited reported of imbalance in drop-outs and data analysis. Economic data reported in another publication. RCT with highest number of patients (n=440).	**Acceptable** Patients (ICU) and only 1 (Mepilex Border Sacrum) of the 2 interventions in line with scope. Relevant for some outcomes reported in the scope, including pressure ulcer incidence and AEs. Eligible comparator (standard care). Relevant for use of some standard care components reported in scope, including risk assessment (Braden scale), and pressure redistribution. Non-UK setting (Australia)
Walker 2017 (Walker et al. 2017)	**Acceptable** Sequence generation, allocation concealment, and outcome measurement/reporting were acceptable. Patients and staff not blinded due to nature of treatments; unclear blinding of outcome assessor. Unclear/limited reporting of similarity of groups in prognostic factors and drop-out rates. ITT analysis but unclear how missing data handled. RCT with lowest number of patients (total 77).	**Acceptable** Patients (high-risk; emergency/surgical/medical wards) and intervention in line with scope. Relevant for some outcomes reported in the scope, including incidence of pressure injury and severity, patient comfort and costs. Eligible comparator (standard care). Relevant for use of some standard care components reported in scope, including skin assessment and pressure redistribution. Non-UK setting (Australia)

Study	Internal validity[1]	External validity[2]
Comparative observational studies		
Brindle 2012 (Brindle and Wegelin 2012)	**Low** Cohort recruitment was acceptable. Unclear/limited reporting of treatment procedures and outcome measurement, patient follow-up and precision. Identification of confounding factors was acceptable.	**Acceptable** Patients (high-risk; ICU) and intervention in line with scope. Relevant for 1 outcome reported in the scope: incidence of any stage of pressure ulcer. Eligible comparator (standard care). Relevant for use of some standard care components reported in scope, including skin assessment, repositioning, pressure redistribution, and barrier cream for incontinence. Non-UK setting (USA)
Chaiken 2012 (Chaike n 2012)	**Low** Unclear/limited reporting about patient recruitment, treatment procedures, confounding factors, follow-up and precision. Outcome measurement based on approved procedure (NDNQI) in retrospective control only. Observational study with highest number of patients (total 564).	**Not acceptable** Patients (ICU) and intervention in line with scope, and reports costs. Uncertainty in relevance of clinical outcomes since measured incidence in intervention group but prevalence in comparator. Eligible comparator (standard care). Relevant for use of some standard care components reported in scope, including risk assessment, frequent repositioning, pressure redistribution and skin care. Non-UK setting (USA)
Cubit 2013 (Cubit et al. 2013)	**Low** Unclear/limited reporting about patient recruitment, treatment procedures, identification of confounding factors, and precision. Outcome measurement based on 4-stage system (AWMA approved) in prospective intervention only.	**Acceptable** Patients (high-risk; emergency department) and intervention in line with scope. Patients aged ≥65 years recruited. Relevant for some outcomes reported in the scope, including presence and stage of sacral pressure injuries. Eligible comparator (standard care). Standard care was a prevention plan in the intervention group but a management plan in the control group. Regular skin assessment was routine practice and thus likely to be a component of both prevention and management plans. Non-UK setting (Australia)
Jin 2018, (Jin 2018)	[redacted]	[redacted]
Haisley 2015 (Haisley et al. 2015)	**Low** Unclear/limited reporting about patient recruitment, treatment procedures and outcome measurement, confounding	**Not acceptable** Study reported in a conference poster so limited information. Patients (high-risk; ICU) and intervention in line with scope. Relevant for 1 outcome

Study	Internal validity[1]	External validity[2]
	factors, follow-up and precision. Insufficient information (from poster) to permit judgement. Number of patients in the control group was not reported. Only 31 patients in the intervention group.	reported in the scope: pressure ulcer incidence. Eligible comparator (standard care) but uncertainty in what standard care prevention measures comprised and whether skin assessment was conducted similarly in both groups. Routine skin assessment appears to be additional to standard care. Non-UK setting (USA)
Park 2014 (Park 2014)	**Acceptable** Unclear/limited reporting about patient recruitment, treatment procedures, outcome measurement and precision. All patients followed-up. Outcome measurement based on established guidelines (NPUAP 2009). Identification and statistical analysis of some confounding factors.	**Acceptable** Patients (high-risk; ICU) and intervention in line with scope. Patients aged ≥40 years recruited. Relevant for some outcomes reported in the scope, including pressure ulcer incidence and severity. Eligible comparator (standard care). Relevant for use of some standard care components reported in scope, including regular repositioning and pressure redistribution. Non-UK setting (South Korea)
Richard-Denis 2017 (Richard-Denis et al. 2017a)	**Acceptable** Unclear/limited reporting about patient recruitment, treatment procedures, outcome measurement, consideration of confounding factors, and precision. Potential confounding factors identified. Outcome measurement based on established guidelines (NPUAP 2007). Patient follow-up was not applicable for critical appraisal due to the study design. Imbalance in patient numbers between groups (89 intervention vs 286 control).	**Acceptable** Patients (surgical spinal trauma) and intervention in line with scope. Relevant for some outcomes reported in the scope, including pressure ulcer incidence and stage. Eligible comparator (prevention protocol). Relevant for use of some standard care components reported in scope, including: risk assessment, repositioning and pressure redistribution in the pre-operative setting. There were slight differences between the intervention and control groups in post-operative measures. Non-UK setting (Canada)
Santamaria 2015b (Santamaria et al. 2015b)	**Acceptable** Cohort recruitment was acceptable. Unclear/limited reporting about treatment procedures, outcome measurement, confounding factors, follow-up and precision. Approved definitions (AWMA) were used to measure outcomes and inter-rater reliability was tested.	**Acceptable** Patients (ICU) and intervention in line with scope. Relevant for some outcomes reported in the scope, including incidence of pressure ulcers and ease of use of product. Eligible comparator (standard care). Relevant for use of some standard care components reported in scope, including: risk assessment, regular repositioning and pressure redistribution. Non-UK setting (Australia)
Yoshimura 2016 (Yoshimura et al. 2016)	**Acceptable** Cohort recruitment was acceptable. Unclear/limited reporting about treatment procedures, outcome measurement, and precision. Both types of dressing compared in the same person. Identification and statistical analysis of many confounding factors. Outcome measurement	**Not acceptable** Patients (spinal surgery) and intervention, applied at only 1 (ileal crest) of the 2 sites, in line with scope. Relevant for 1 outcome reported in the scope: incidence of intraoperative pressure ulcers. Eligible comparator (Opsite Flexifix hydrocolloid dressing with standard positioning protocol). Uncertain relevance to standard care in scope as the standard

Study	Internal validity[1]	External validity[2]
	based on established guidelines (NPUAP 2014). All patients followed-up.	positioning protocol used in both groups tailored pressure redistribution to patient requirements relating to the surgical frame used. Unclear what other prevention measures were in place. Non-UK setting (Japan)

Grey shading indicates that the paper is available as an abstract/poster only.
Yellow shading reflects information submitted under 'academic in confidence' and corresponding EAC comments on this study.

1: Overall internal validity for each study has been assessed as 'High', 'Acceptable' or 'Low'.
For RCTs:
A rating of 'High' was assigned if ≥3 key criteria (sequence generation, allocation concealment, blinding) were met and ≤1 of all other criteria were unclear/not met.
A 'Acceptable' rating was assigned to those reporting met/unclear judgements for the majority of criteria.
A 'Low' rating was assigned if ≥2 key criteria (sequence generation, allocation concealment, blinding) or the majority of all criteria were not met.

For observational studies:
A 'High' rating was assigned if all 3 key criteria (patient group, measurement of exposure, measurement of outcome) were met and established guidelines were used in both groups.
An 'Acceptable' rating was assigned to those with established guideline use and ≥1 criteria met.
A 'Low' rating was assigned if ≥2 key criteria and the requirement for use of established guidelines were unclear/not met.

2: Overall external validity for each study has been assessed as 'Acceptable' or 'Not acceptable'.
'Not acceptable' has been assigned if there is any uncertainty in the relevance of the patients, intervention, comparator, or outcomes in relation to the scope, or the study report is an abstract/poster with limited information.
All others have been rated as 'Acceptable'.

Abbreviations: AE, adverse event; AMWA, Australian Wound Management Association; ICU, intensive care unit; ITT, intention-to-treat; NDNQI, National Database of Nursing Quality Indicators; NPUAP, National Pressure Ulcer Advisory Association; RCT, randomized controlled trial.

Randomized controlled trials

The EAC noted that 2 of the 4 studies had prospectively registered trial protocols on online, international clinical trials registry databases, ClinicalTrials.gov (Santamaria (2015a)) and the Australian New Zealand Clinical Trials Registry (ANZCTR) (Walker (2017)), which aids research transparency. There is a potential for publication bias in the 2 studies that did not have published protocols (Aloweni et al. 2017, Kalowes et al. 2016). Two studies (Kalowes et al. 2016, Santamaria et al. 2015a) declared no competing financial interests or did not report their funding status. The remaining 2 studies (Aloweni et al. 2017, Walker et al. 2017) were funded by organizations other than Mölnlycke Health Care (i.e. the company). In the absence of any reported involvement with the company, the potential for a bias towards Mepilex Border

dressings in the non-blinded assessment and reporting of outcomes is likely reduced.

All 4 studies (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a, Walker et al. 2017) described randomisation procedures that should produce comparable groups of patients allocated to each treatment, such as computer-generated random numbers, online clinical trial coordinating website, and randomisation program. Methods used to conceal the allocation sequence from patients and clinical personnel, such as central allocation and pre-prepared envelopes, were also reported. However, in 1 study (Santamaria et al. 2015a) that used pre-prepared assignment envelopes it was unclear whether sequentially numbered, opaque, sealed envelopes were used. This increases the potential for selection bias as treatment assignments could have been foreseen during the enrolment process.

Blinding of the patients and the clinical personnel was not possible given the nature of the treatments being compared in the 4 studies: a dressing (plus standard care) versus standard care alone. One study (Walker et al. 2017) used an off-site nurse assessor blinded to the intervention to assess high-resolution photographs for skin assessment, but this was of limited success since the dressings tended to leave marks on the skin. In another study (Santamaria et al. 2015a), the research team had undergone inter-rater reliability testing prior to outcome measurement to ensure consistency in assessment, but it was unclear whether any such tests were conducted during the assessment period. Thus, in all 4 studies there is a risk for performance and detection bias in the reported findings since the allocated treatments are known.

Patients' demographics and physiological characteristics between the Mepilex Border Sacrum and standard care alone groups were considered comparable at baseline in 3 studies (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a), with 2 studies reporting no statistically significant differences in the characteristics analysed (Aloweni et al. 2017, Kalowes et al. 2016). In the remaining study (Walker et al. 2017), which reported median values for many factors, the groups were reasonably well matched on most characteristics aside from gender and obesity based on BMI value; low or high BMI is a risk factor for developing pressure ulcers (see Section 2.1.1). The comparator (routine care alone) contained significantly higher proportions of females and obese patients than the Mepilex Border Sacrum group, although there were a lot of missing data on BMI. This heterogeneity increases the potential risk of bias. The authors noted, as a limitation of their study, that the larger sized version of the dressing was not available at the time the study was conducted.

All 4 studies presented CONSORT flow diagrams depicting the patient flow through the study. Drop-out levels between the treatment groups were similar

in 1 study (Kalowes et al. 2016) and unclear due to reporting limitations in 2 studies (Santamaria et al. 2015a, Walker et al. 2017), which made it difficult to assess whether there was any variation across treatment arms. In the remaining study (Aloweni et al. 2017) there were imbalances in drop-outs between groups for a variety of reasons: early termination from the study due to diarrhoea and treatment contamination was higher in the intervention group; early termination due to actively dying/death was higher in the control group; and requests for study withdrawal and drop-outs due to sacral excoriation were roughly similar between groups. Analyses were conducted by intention-to-treat (ITT) in 2 studies (Aloweni et al. 2017, Kalowes et al. 2016), while another study reported ITT analysis but excluded patients who were randomized in error or revoked consent. The remaining study (Santamaria et al. 2015a) did not conduct ITT analysis contrary to the methodology; the number of patients analysed in each group was few than the number randomized. None of the studies reported data imputation methods for handling missing data. The lack of reasons behind drop-outs in some of the studies and the exclusion of patients from the analysis both increase the risk of attrition bias in the results.

Aside from 1 study (Santamaria et al. 2015a) that reported its cost data in a separate publication of an economic analysis, there was no apparent evidence of selective reporting that could potentially increase the risk of bias in the results: all outcome measures pre-specified in the published articles (Aloweni et al. 2017, Kalowes et al. 2016) or published protocol (Walker et al. 2017) were reported.

The EAC noted that power calculations were performed in 3 studies (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a) to inform the sample size necessary for primary outcome measurement and the testing of the null hypothesis. In 2 studies (Kalowes et al. 2016, Santamaria et al. 2015a) this matched the sample size that had been estimated. In the third study (Aloweni et al. 2017) the number of patients recruited was lower than the estimated sample size. The authors acknowledged the study was slightly underpowered, saying that the trial had ended prematurely due to limited resources. A power calculation was not performed in the remaining study (Walker et al. 2017). The authors reported the small sample size as a limitation of their study, but considered it sufficient for the purpose of a feasibility study to inform a larger trial.

All 4 RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a, Walker et al. 2017) provided acceptable levels of external validity and are therefore considered applicable to the scope. The studies reported patients and treatments that were in line with the scope and presented data on several relevant outcomes. The EAC considered that the results from these studies were generalisable to patients in acute care settings who were at risk or high-

risk of pressure ulceration. However, there is great variation in the definition of standard care, not just on a national basis, but also at the local level and within different care settings and, therefore, across studies, which will impact on generalisability. In addition, studies may have reported only the main components of their standard care programmes, and it was not entirely clear whether all patients received exactly the same programme, or a more individualised approach tailored to the patient's need. As such, the components of standard care might not always be aligned with those described in the scope.

There was less variation across studies in terms of how they categorised/staged pressure ulcers, with 2 studies (Aloweni et al. 2017, Kalowes et al. 2016) using the NPUAP (2014) guidelines, in line with the scope, 1 study (Walker (2017)) using an earlier version of NPUAP/EPUAP guidelines reported by the AMWA in 2012, and the remaining study (Santamaria et al. 2015a) using an AMWA 4-point staging system from 2001 (Murray LD et al. 2001). Earlier versions of the NPUAP guidelines (NPUAP 2007; NPUAP 2009) and the AMWA (2001) system appear consistent with NPUAP guidelines which are widely used across the NHS. All 4 studies were also based at single-sites, which will further limit their generalisability.

One study (Kalowes et al. 2016) had a high level of internal validity, while the other 3 studies (Aloweni et al. 2017, Santamaria et al. 2015a, Walker et al. 2017) had an acceptable level of internal validity. Any limitations in the internal validity of the studies should be taken into consideration when interpreting the results.

The EAC also notes that all 4 studies were conducted in non-UK settings, with 2 based in Australia (Santamaria et al. 2015a, Walker et al. 2017), 1 (Aloweni et al. 2017) in Singapore, and 1 (Kalowes et al. 2016) in USA, which may potentially limit their overall usefulness.

Comparative observational trials

Nine comparative observational trials have been appraised. One of these, an observational trial (Haisley et al. 2015), has been subsequently excluded from the narrative appraisal given the limited information reported in the conference poster, but it has been included in the associated tables for information purposes.

[redacted] and 4 declared no conflicts of interest or financial disclosures (Brindle and Wegelin 2012, Chaiken 2012, Park 2014, Yoshimura et al. 2016). One study (Richard-Denis et al. 2017a) received funding from the US Army, whilst 2 studies declared funded from Mölnlycke Health Care (i.e. the company) (Cubit et al. 2013, Santamaria

et al. 2015b), thus increasing the potential for bias as clinical personnel cannot be blinded to the treatment, although 1 of these studies (Cubit et al. 2013) stated that Mölnlycke Health Care had no contact with the patients and was not involved in data collection or analysis.

Cohort recruitment was considered acceptable in 3 studies (Brindle and Wegelin 2012) (Santamaria et al. 2015b, Yoshimura et al. 2016), with clear eligibility criteria applied during the enrolment process and, additionally, in 1 study an assignment procedure based on predesignated rooms and room availability on transfer from the operating room (Brindle and Wegelin 2012). Patient demographics at baseline between the Mepilex Border Sacrum/Heel groups and standard care alone group were considered similar in 2 of these studies (Brindle and Wegelin 2012, Santamaria et al. 2015b), with no statistically significant differences reported. The third study (Yoshimura et al. 2016) was a bilateral comparison of Mepilex Border and Opsite flexifix) dressings in each individual patient. Five studies (Chaiken 2012, Cubit et al. 2013, Jin 2018, Park 2014, Richard-Denis et al. 2017a) reported limited information on how their cohorts were recruited. In particular, it was unclear to the EAC whether the same eligibility criteria had been applied to both the intervention group and retrospective control in 2 studies (Chaiken 2012, Jin 2018) and to groups recruited over 2 sequential time periods in another study (Richard-Denis (2017)) in which an imbalance in patient numbers was evident across groups. Potential confounding factors and their possible impact on outcomes were generally not well reported. Three studies (Brindle and Wegelin 2012, Park 2014, Richard-Denis et al. 2017a) identified confounding factors and reported appropriate statistical analysis, while a further study (Richard-Denis et al. 2017a) of Mepilex Border versus a gel mattress analysed potential risk factors but did not consider the impact of using an alternative to the gel mattress (as part of standard care) when interpreting the results. Information on confounding factors in the remaining studies was either unclear or insufficient for the EAC to pass judgement.

The description of the treatment procedures and how the outcomes were measured was limited or unclear across all studies, with inconsistent reporting of the procedures used to apply treatments, components of standard care in both groups, and details of clinical personnel and skin assessments (including assessment timings). In particular, outcome measurement was not considered acceptable in 3 studies (Chaiken 2012, Cubit et al. 2013, Jin 2018) since different methods of skin assessment were employed in the intervention group and retrospective control. The EAC noted that only 4 studies assessed outcomes of skin assessment in both groups using identical methods based on approved definitions or established guidelines: Australian Wound Management Association (AWMA) definitions (Santamaria et al. 2015b), NPUAP (2007) (Richard-Denis et al. 2017a), NPUAP (2009) (Park 2014) and NPUAP (2014)

(Yoshimura et al. 2016). Details of follow-up were poorly reported in the majority of studies, with only 3 studies (Jin 2018, Park 2014, Yoshimura et al. 2016) reporting complete follow-up and patients accounted for in the analysis. In general, information relating to exposure and outcome measurement, outcome definitions, and follow-up were deemed to unclear/limited to inform an assessment by the EAC.

The presentation and precision of the results was unclear in all studies and reporting of standard deviations, confidence intervals, or other statistical analysis of the results was limited. One study (Brindle and Wegelin 2012) reported p-values and hazard ratios with confidence intervals, 1 study (Yoshimura et al. 2016) reported standard deviations but provided odds ratios with confidence intervals for only a few of the risk factors analysed, and another study (Chaiken 2012) was unable to compare the groups directly since they used different outcome measures. Overall, there is insufficient information available for the EAC to comment on the precision of the results.

Three studies (Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b) provided acceptable levels of both internal and external validity and are considered applicable to the scope, aside from the issues relating to variation in standard care highlighted in the appraisal of RCTs. The studies reported patients and treatments that were in line with the scope and presented data on several relevant outcomes, although recruitment was restricted to patients aged ≥40 years in 1 study (Park 2014). However, all 3 studies were conducted at single sites located outside of the UK (South Korea, Canada, Australia), which impacts generalisability to other settings and may limit their potential usefulness.

A further 2 studies (Brindle and Wegelin 2012, Cubit et al. 2013) were considered to have low levels of internal validity but acceptable levels of external validity and were considered to be applicable to the scope. In both studies the patients and treatments were relevant to the scope and data for 1 or 2 outcomes were reported. However, they were conducted at single sites outside of the UK, in Australia (Cubit et al. 2013) and USA (Brindle 2010), and 1 (Cubit et al. 2013) only enrolled patients aged ≥65 years. These factors impact generalisability and overall usefulness to the decision problem.

One study (Yoshimura et al. 2016) was considered to have an acceptable degree of internal validity but not external validity. The study investigated 2 types of dressing using a split-body comparison in patients undergoing elective spinal surgery in the prone position using a Relton-Hall frame in conjunction with the standard positioning protocol, but no other described standard care. This limits the generalisability to other institutions and the use of dressings in

other surgical positions and with other surgical procedures. The study was non-UK based (Japan), which may also limit its potential usefulness.

A further 2 studies (Chaiken 2012, Jin 2018) were considered to have limited value in relation to the decision problem and neither provided acceptable levels of internal or external validity. In Chaiken et al. (Chaiken 2012) the patients and treatment are in line with the scope but the outcomes measures were different in the dressing group (incidence) and retrospective control (prevalence). [redacted] Both studies were also conducted outside of the UK, in USA (Chaiken 2012) and [redacted], thus reducing their potential usefulness.

3.6 Results

3.6.1 Critique of company's report of results

The company completed Table B9 for each included study in Section 7.6.1 of the submission. The EAC has checked the company's tabulated results of the included studies against the original published data. Only the results from studies included based on the EAC's revised eligibility criteria (see Table 3.1) were checked. Only minor issues were identified by the EAC and these are summarised in Appendix F.

The company reported in Section 7.6.2 of the submission that 4 of the included studies (Brindle and Wegelin 2012, Lientz 2013, Sullivan 2015, Walsh et al. 2012) reported per protocol rather than ITT analysis. Given that Brindle & Wegelin 2012 (Brindle and Wegelin 2012) is now the only included study based on the EAC's revised eligibility criteria, the other 3 studies (Lientz 2013, Sullivan 2015, Walsh et al. 2012) are not considered any further in the current assessment report.

3.6.2 EAC's report of results

The results of the studies included by the EAC are summarised by outcome in the following sections. Four studies (Chaiken 2012, Haisley et al. 2015, Jin 2018, Yoshimura et al. 2016) were considered to provide unacceptable levels of external validity (see Section 3.5.2) and hence were excluded from further discussion in this assessment report. The results reported in this section are, therefore, based on 4 RCTs and 5 non-randomised comparative studies.

Incidence of developing pressure ulcers

Results for the incidence of pressure ulcers were reported in all 4 RCTs and 5 non-randomised comparative studies.

Three of the 4 RCTs reported incidence data based on the number of patients developing pressure ulcers during the study period. These 3 RCTs compared patients receiving Mepilex Border Sacrum dressings with patients receiving standard care. In 1 RCT (Santamaria 2015a), authors report the number of pressure ulcers that developed but did not report the number of patients who developed pressure ulcers. The results are summarised below in

Table ***3.5***.

Table 3.5: Results of the EAC's included RCTs: Incidence of pressure ulcers (proportion of patients who developed pressure ulcers)

Study	Follow-up	Patients	Proportion (n, %) of patients who developed PUs	Relative risk of pressure ulcer (Mepilex Border v. SC)
Aloweni 2017 (Aloweni et al. 2017)	Every 3 days up to 14 days	**Mepilex Border Sacrum + SC**: 129 patients **SC alone**: 202 patients	**Mepilex Border Sacrum + SC**: 5 (3.9%) patients **SC alone**: 10 (5%) patients p = 0.84	RR 0.78 [95% CI 0.27 to 2.24]*
Kalowes 2016 (Kalowes et al. 2016)	Daily throughout ICU stay and 6 months after discharge	**Mepilex Border Sacrum + SC:** 184 patients **SC:** 182 patients	**Mepilex Border Sacrum:** 1 (0.5%) patients **SC:** (3.8%) 7 patients Poisson regression, p=0.01	RR 0.14 [95% CI 0.02 to 1.14]*
Walker 2017 (Walker et al. 2017)	NR.	**Mepilex Border Sacrum + SC**: 39 patients **SC:** 38 patients	**Mepilex Border Sacrum + SC:** 1 (2.5%) **SC:** 1 (2.5%)	RR 0.97 [95% CI 0.06 to 15.02]*
Santamaria 2015a (Santamaria et al. 2015a)	Until discharge	**Mepilex Border Sacrum + SC:** NR **SC**: 221 (152 analysed)	NR	NA

Abbreviations: NA, not applicable; NR, not reported; PU, pressure ulcer; RCTs, randomised controlled trial; RR, relative risk; SC, standard care
*Calculate by the reviewers

In 2 of the RCTs (Aloweni et al. 2017, Kalowes et al. 2016), a lower number of patients developing pressure ulcers was observed in the Mepilex Border Sacrum group. The difference was statistically significant in 1 RCT, only (Kalowes et al. 2016). In Kalowes 2016 (Kalowes et al. 2016), the authors also reported the cumulative incidence rate of hospital acquired pressure ulcers (HAPUs) calculated per 1000 patient days at risk. The cumulative incidence of HAPUs was significantly lower in the Mepilex Border Sacrum group with an incidence rate of 0.7 per 1000 patient days compared with 5.9 in the control group (incidence rate ratio 0.12 (95% CI 0.02-1.00) p=0.01). In Walker 2017 (Walker et al. 2017), 1 patient in each group developed a pressure ulcer. However, the authors reported that a further patient in the Mepilex Border Sacrum group developed a pressure ulcer but this was not agreed by the independent assessor. In the Santamaria 2015a (Santamaria et al. 2015a), only the incidence data reported for patients who received Mepilex Border Sacrum are relevant to the scope (see Section 3.6.1). This data, however, are quite

limited. The authors reported that 2 pressure ulcers developed in patients receiving Mepilex Border Sacrum compared with 8 which developed in patients receiving standard care. The number of patients who developed pressure ulcers at the sacrum, however, was not reported. The EAC contacted the authors of this publication to determine how many patients developed pressure ulcers at the sacrum in each arm of the study, but to date has received no response.

Five non-randomised comparative studies (Brindle and Wegelin 2012, Cubit et al. 2013, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b) reported the proportion of patients that developed pressure ulcers during the study period. Two studies (Brindle and Wegelin 2012, Cubit et al. 2013) compared patients receiving Mepilex Border Sacrum with patients receiving standard care. One study (Richard-Denis et al. 2017a) compared patients receiving Mepilex Border Sacrum with patients receiving a gel mattress. One study (Park 2014) compared patients receiving Mepilex Border dressings (applied to the sacrum) with patients who received standard care. One study (Santamaria et al. 2015b) compared patients receiving Mepilex Border Heel with the group of patients receiving standard care in the prior BORDER trial (Santamaria et al. 2015a). The results are presented below in Table 3.6.

Table 3.6: Results of the EAC's included non-randomised comparative studies: Incidence of pressure ulcers (proportion of patients that developed pressure ulcers)

Study	Follow up	Patients	Proportion (n, %) of patients who developed PUs	Relative risk of pressure ulcer (Mepilex Border v. standard care)
Brindle & Wegelin 2012 (Brindle and Wegelin 2012)	Daily until they left the ICU or were removed from the study	**Mepilex Border Sacrum + SC:** 59 enrolled patients (50 analysed patients) **SC:** 39 enrolled patients (35 analysed patients)	**Mepilex Border Sacrum + SC:** 1 (2%) patient **SC:** 4 (11.7%) patients p = 0.185	RR 0.17 [95% CI 0.02 to 1.50]
Cubit 2013 (Cubit et al. 2013)	Every 8 hours for duration of hospital stay or until the end of trial	**Mepilex Border Sacrum +SC:** 51 patients **SC:** 58 patients	**Mepilex Border Sacrum + SC:** 1 patient (1.96%) **SC:** 6 patients (10.34%) p = ≤0.08	RR = 0.13
Park 2014 (Park 2014)	Every 3 days for the duration of the study	**Mepilex Border** (applied to the sacrum) **+SC**: 52 patients **SC:** 50 patients	**Mepilex Border** (applied to the sacrum) **+ SC**: 3 (6%) patients **SC:** 23 (46%) patients	RR = 0.19

Study	Follow up	Patients	Proportion (n, %) of patients who developed PUs	Relative risk of pressure ulcer (Mepilex Border v. standard care)
			p = <0.001	
Richard-Denis 2017 (Richard-Denis et al. 2017a)	Every 8 hours in dressing group (unclear in gel mattress group) until discharge	**Mepilex Border Sacrum + SC:** 89 patients **Gel mattress + SC:** 226 patients	**Mepilex Border Sacrum + SC:** 17 (19.1%) patients **Gel mattress + SC:** 40 (17.1%) patients p = 0.77	RR = 1.08
Santamaria 2015 (BORDER II) (Santamaria et al. 2015b)	Daily until discharge	**Mepilex Border Heel:** 191 enrolled patients (150 analysed patients) **SC** (from BORDER trial)**:** 221 enrolled patients (152 analysed patients	**Mepilex Border Heel:** 0 (0%) patients **SC** (from BORDER trial): 14 (9.2%) patients p = <0.001	RR = 0.00
Abbreviations: PU, pressure ulcer; RR, relative risk; SC, standard care				

In 2 studies (Brindle and Wegelin 2012, Cubit et al. 2013) a lower number of patients developed pressure ulcers in the Mepilex Border Sacrum group compared with patients receiving standard care, however, this difference was only statistically significant in Cubit (2013) (p=≤0.08). Similarly, in Richard-Denis 2017 (Richard-Denis et al. 2017a), fewer patients developed pressure ulcers in the Mepilex Border Sacrum group than those in the gel mattress group. However, the groups in this study (Richard-Denis et al. 2017a) were considerably imbalanced in terms of patient numbers (89 received Mepilex Border Sacrum and 286 received the gel mattress) and the difference between the 2 groups was not statistically significant (p=0.77). In Park 2014), a lower proportion of patients developed pressure ulcers in the Mepilex Border group compared with those receiving standard care (p<0.001). In Santamaria 2015b (Santamaria et al. 2015b) no patients developed pressure ulcers in the Mepilex Border Heel group compared with 14 patients (9.2%) who developed pressure ulcers in standard care (p<0.001).

Three of the nonrandomised comparative studies (Brindle and Wegelin 2012, Cubit et al. 2013, Santamaria et al. 2015b) reported the specific number of pressure ulcers developed amongst the affected patients. Across these studies, the number of pressure ulcers was lower in the Mepilex Border Sacrum/ Mepilex Heel groups compared with standard care. These results are summarised in Table 3.7.

Table 3.7: Results of the EAC's included non-randomised comparative studies: Incidence of pressure ulcers (number of pressure ulcers developed amongst affected patients)

Study	Follow up	Patients	Proportion (n, %) of patients who developed PUs	n PUs developed amongst affected patients
Brindle & Wegelin 2012 (Brindle and Wegelin 2012)	Daily until they left the ICU or were removed from the study	**Mepilex Border Sacrum + SC:** 59 enrolled patients (50 analysed patients) **SC:** 39 enrolled patients (35 analysed patients)	**Mepilex Border Sacrum + SC:** 1 (2%) patient **SC:** 4 (11.7%) patients p = 0.185	**Mepilex Border Sacrum + SC:** 1 pressure ulcer **SC:** 8 pressure ulcers
Cubit 2013 (Cubit et al. 2013)	Every 8 hours for duration of hospital stay or until the end of trial	**Mepilex Border Sacrum + SC:** 51 patients **SC:** 58 patients	**Mepilex Border Sacrum + SC:** 1 patient (1.96%) **SC:** 6 patients (10.34%) p = ≤0.08	**Mepilex Border Sacrum + SC:** 1 pressure ulcer **SC:** 6 pressure ulcers
Santamaria 2015 (BORDER II) (Santamaria et al. 2015b)	Daily until discharge	**Mepilex Border Heel + SC:** 191 enrolled patients (150 analysed patients) **SC** (from BORDER trial)**:** 221 enrolled patients (152 analysed patients	**Mepilex Border Heel + SC:** 0 (0%) patients **SC** (from BORDER trial): 14 (9.2%) patients p = <0.001	**Mepilex Border Heel + SC:** 0 pressure ulcers **SC** (from BORDER trial): 19 pressure ulcers
Abbreviations: PU, pressure ulcer; RR, relative risk; SC, standard care				

Stage of pressure ulcer developed

Results relating to the stage of pressure ulcers that developed amongst patients were reported in 3 of the 4 RCTs and 5 non-randomised comparative studies. The results are summarised below in Table 3.8.

Table 3.8: Results of the EAC's included studies: Stage of pressure ulcer developed

Study	Patients	Proportion (n, %) of patients who developed PUs	Stage of PU developed
RCTs			
Aloweni 2017 (Aloweni et al. 2017)	**Mepilex Border Sacrum + SC**: 129 patients **SC alone**: 202 patients	**Mepilex Border Sacrum + SC care**: 5 (3.9%) patients **SC alone**: 10 (5%) patients	All pressure ulcers assumed to be stage I. The authors reported that any stage I pressure injuries (as

Study	Patients	Proportion (n, %) of patients who developed PUs	Stage of PU developed
		p = 0.84	classified by NPUAP and EPUAP) were reported as an incident
Kalowes 2016 (Kalowes et al. 2016)	**Mepilex Border Sacrum + SC:** 184 patients **SC:** 182 patients	**Mepilex Border Sacrum + SC:** 1 (0.5%) patients **SC:** (3.8%) 7 patients	**Mepilex Border Sacrum + SC**: DTI = 1 (100%) **SC**: DTI = 1 (14%); unstageable = 2 (29%); stage II = 4 (43%)
Walker 2017 (Walker et al. 2017)	**Mepilex Border Sacrum + SC**: 39 patients **SC:** 38 patients	**Mepilex Border Sacrum + SC:** 1 (2.5%) **SC:** 1 (2.5%)	**Mepilex Border Sacrum + SC:** Stage I = 1 (100%) **SC:** Stage I = 1 (100%)
Non-randomised comparative studies			
Brindle & Wegelin 2012 (Brindle and Wegelin 2012)	**Mepilex Border Sacrum + SC:** 59 enrolled patients (50 analysed patients) **SC:** 39 enrolled patients (35 analysed patients)	**Mepilex Border Sacrum + SC:** 1 (2%) patient **SC:** 4 (11.7%) patients (8 pressure ulcers) p = 0.185	**Mepilex Border Sacrum + SC:** DTI = 1 (100%) **SC:** DTI = 5 (63%); stage II = 3 (38%); stage III = 3 (38%)
Cubit 2013 (Cubit et al. 2013)	**Mepilex Border Sacrum +SC:** 51 patients **SC:** 58 patients	**Mepilex Border Sacrum + SC:** 1 patient **SC:** 6 patients p = ≤0.08	**Mepilex Border Sacrum + SC:** Stage II = 1 (100%) **SC:** Stage I or II = 6 (100%)
Park 2014 (Park 2014)	**Mepilex Border** (applied to the sacrum) **+ SC**: 52 patients **SC:** 50 patients	**Mepilex Border** (applied to the sacrum) **+ SC**: 3 (6%) patients **SC:** 23 (46%) patients p = <0.001	**Mepilex Border** (applied to the sacrum) **+ SC**: Stage I = 1 (33%); stage II = 1 (33%); DTI = 1 (33%) **SC:** Stage I = 17 (74%); stage II = 6 (26%)
Richard-Denis 2017 (Richard-Denis et al. 2017a)	**Mepilex Border Sacrum + SC:** 89 patients **Gel mattress + SC:** 226 patients	**Mepilex Border Sacrum + SC:** 17 (19.1%) patients **Gel mattress + SC:** 40 (17.1%) patients p = 0.77	**Mepilex Border Sacrum + SC:** Stage I = 29.4% (5); stage II = 70.6% (12) **Gel mattress + SC:** Stage I = 30% (12); stage II = 62.5% (25); stage III = 2.5% (1); stage IV = 5% (2)
Santamaria 2015 (BORDER II) (Santamaria et al. 2015b)	**Mepilex Border Heel +SC:** 191 enrolled patients (150 analysed patients) **SC** (from BORDER trial)**:** 221 enrolled patients (152 analysed patients	**Mepilex Border Heel + SC:** 0 (0%) patients **SC** (from BORDER trial): 14 (9.2%) patients (19 pressure ulcers) p = <0.001	**Mepilex Border Heel + SC:** NR. **SC** (from BORDER trial): Stage I = 15 (79%); stage II = 2 (11%); stage IV = 2 (11%)
Abbreviations: PU, pressure ulcer; RCT, randomised controlled trial; RR, relative risk; SC, standard care			

In the Aloweni 2017 trial (Aloweni et al. 2017), the authors reported that any stage I pressure injuries, as classified by the NPUAP/EPUAP 2014, were reported as an incident. Therefore, it can be assumed that all pressure ulcers in this trial were at least stage I. However, it is unclear if pressure ulcer severity evolved throughout the study period. In the Kalowes 2016 trial (Kalowes et al. 2016), pressure ulcers were staged according to NPUAP 2014. The pressure ulcer that developed in the single patient receiving Mepilex Border Sacrum in this trial (Kalowes et al. 2016) was assessed as DTI. Amongst patients in the standard care group, 1 was assessed as DTI, 2 were assessed as stage II and 3 were deemed unstageable. The assessment of pressure ulcers in the Walker 2017 trial were guided by the NPUAP and EPUAP. Of the 2 patients developing pressure ulcers in this trial (one each in the Mepilex Border Sacrum and standard care groups), both were assessed as stage I.

In Brindle & Wegelin 2012 (Brindle and Wegelin 2012), results for pressure ulcer stage amongst patients are reported. However, the authors do not explicitly report what criteria was used to assess pressure ulcer severity (see Section 3.4). The pressure ulcer that developed in the patient receiving Mepilex Border Sacrum was assessed as DTI and the authors stated that it did not evolve into a higher stage pressure ulcer. Of the standard care group, 5 were assessed as DTI, 3 as stage II and 3 as stage III.

In Cubit 2013 (Cubit et al. 2013), pressure ulcers were assessed according to the AMWA 4-stage system. The pressure ulcer that developed in the single patient who received Mepilex Border Sacrum was assessed as stage II. Of the 6 patients developing pressure ulcers in the standard care group, the pressure ulcers were assessed as either stage I or stage II. In Park 2014 (Park 2014), pressure ulcers were assessed according to NPUAP 2009. Of the 3 patients developing pressure ulcers in the Mepilex Border group, 1 was assessed as stage I, 1 as stage II and 1 as DTI. Of the 23 patients developing pressure ulcers in standard care, 17 were assessed as stage I and 6 as stage II.

In Richard-Denis 2017 (Richard-Denis et al. 2017a), pressure ulcer development and staging was assessed using NPUAP 2007. Of the 17 patients developing pressure ulcers in the Mepilex Border Sacrum group, 5 were assessed as stage I and 12 were assessed as stage II. Of the 40 patients developing pressure ulcers in the gel mattress group, 12 were assessed as stage I, 25 as stage II, 1 as stage III and 2 as stage IV. In the Santamaria 2015b study (Santamaria et al. 2015b), pressure ulcers were identified and categorised using the AWMA 4-stage system. Staging was not reported for the Mepilex Border Heel patient group, as 0 patients developed pressure ulcers. Of

the 14 patients developing pressure ulcers in the standard care group, 15 were assessed as stage I, 2 as stage II and 2 as stage IV.

Patient comfort and satisfaction

Although not pre-specified by the authors as an outcome, the Walker 2017 trial (Walker et al. 2017) presents results for patient comfort/satisfaction. Patient self-assessments of dressing comfort were sought and documented on 131 occasions. The results showed that in 95% of occasions (125 out of 131), patients reported the dressing as comfortable. In 5% of occasions (6 out of 131), patients reported discomfort with the dressing.

No other included studies reported relevant results in relation to this outcome.

Ease of use

Although not pre-specified as an outcome, usability of the Mepilex Border Heel dressing was discussed by the authors in the Santamaria 2015b (Santamaria et al. 2015b) study publication. In particular, the authors reported that the adhesive border tabs and margins rolled up easily and were difficult to unravel after being partially peeled back for skin inspection. This reportedly made reapplying the dressing difficult. Further, it was reported that the foam dressing was difficult to maintain in place if the patient was restless or agitated, and soon dislodged if the adhesive border started to roll.

No other included studies reported relevant results in relation to this outcome.

Complications and device related adverse events

There were very limited data reported across the included studies in relation to complications and device-related adverse events. In the Kalowes 2016 trial (Kalowes et al. 2016), the authors reported that no adverse events related to the experimental dressing (i.e. Mepilex Border Sacrum) were identified. Similarly, in the Santamaria 2015a trial (Santamaria et al. 2015a), the authors reported there were no adverse events relating to the dressings. In the Aloweni 2017 trial (Aloweni et al. 2017), the authors reported the number and reasons for patient dropouts. Two of the reasons reported were:

- Sacral excoriation: 3 patient dropouts in the Mepilex Border Sacrum + SC group vs 2 patient dropouts in the standard care group.
- Contamination of treatment: 9 patient dropouts in the Mepilex Border Sacrum + SC group vs 1 patient dropouts.

No further details on complications and device-related adverse events were reported across the included studies.

There were no relevant data reported across the included studies for any other outcomes of interest defined in the NICE scope.

Subgroup data

There were no subgroups reported in the NICE scope. However, the subgroup identified below has still been considered as it may be of relevance based on the overall population of interest.

Braden Score < 12 vs. Braden score of 13 & 14

Incidence of developing pressure ulcers

In the Aloweni 2017 trial (Aloweni et al. 2017), a subgroup analysis was conducted with patients categorised according to their Braden score. The results showed no significant difference between the Mepilex Border Sacrum and standard care groups in the Braden score 13 & 14 (i.e. lower risk) patient subgroup. However, a significant difference was observed between Mepilex Border Sacrum and the standard care group ($p = 0.04$) in the Braden score ≤12 (i.e. higher risk) subgroup.

3.7 Description of the adverse events

Data on all outcomes, including device-related AEs, for the studies included in the EAC review have been reported in Section 3.6. None of the single-arm studies identified (listed in Appendix G) reported any AEs of relevance.

In its submission, the company reported [redacted]The company conducted an additional separate review of adverse events, but all 4 studies included in the narrative synthesis evaluated Mepilex Border products in healthy volunteers, a population outside of the scope of the decision problem. The company also presented a limited qualitative review of the few studies included in the company submission (Sections 7.1-7.6) that reported clinical data on adverse events, although most did not pre-specify these as outcomes. In the general absence of adverse events that could be definitely associated with use of the dressing, the company highlighted withdrawals due to treatment contamination in 1 study as a potential safety concern in poorly managed incontinent patients. Withdrawals due to sacral excoriation, obtained from the same study, were reported in a table but not commented on further; these are unlikely to be related specifically to

Mepilex Border products since they occurred at a similar frequency across treatment arms. The company also chose to assess the level of pressure ulcers still experienced during prevention studies as an adverse event, although the value of this interpretation of incidence is unclear.

The company conducted additional searches in national regulatory databases and retrieved 1 nurse-reported event from US Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) (Section 7.7.3, Submission), which related to a patient death that could not be definitively linked to the Mepilex Border Sacrum dressing, and reported no data were available from Medicines and Healthcare Products Regulatory Agency (MHRA).

A search of the FDA MAUDE website was conducted by the EAC on 06/04/2018. Date limits were applied to include records from the last 10 years with the brand name 'Mepilex'. One relevant record was identified for Mepilex Border Sacrum dressing which matched the description of the record obtained by the company, in which the dressing was applied to an elderly patient who then went on to develop a suspected deep tissue injury under the dressing and subsequently died. A search of MHRA alerts and recalls for drugs and medical devices was also conducted on 06/04/2018 for 'Mepilex' and no results were returned.

3.8 Description and critique of evidence synthesis and meta-analysis

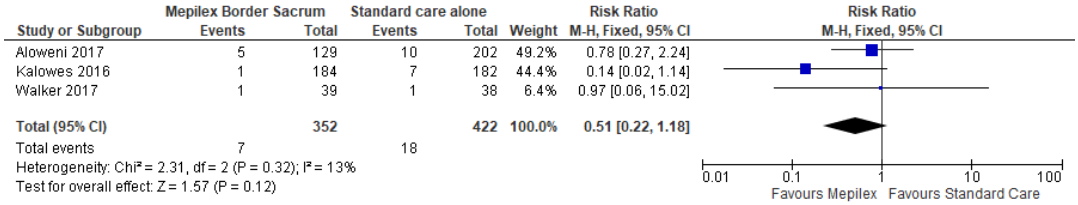
The company did not synthesise the data using meta-analysis due to reported time constraints associated with preparing the submission. Instead the company reported and commented on synthesis conducted by several published systematic reviews. The company also provided a narrative synthesis of results based on the included studies.

The EAC has pooled the results of 3 included RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Walker et al. 2017) in relation to pressure ulcer incidence. A fourth trial, Santamaria 2015a, was considered in a sensitivity analysis only (Santamaria et al. 2015a). This trial reported the number of pressure ulcers that developed among patients rather than the number of patients that developed a pressure ulcer. The EAC note that, based on data reported in other studies patients can develop more than one pressure ulcer at the sacrum at one time.

The 4 trials all compare patients receiving Mepilex Border Sacrum dressings with standard care.

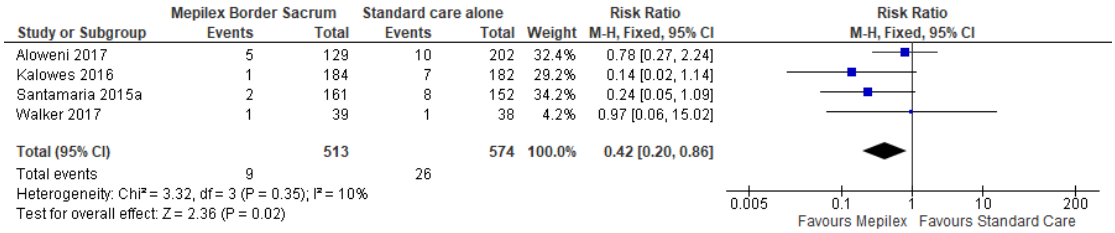
A summary of the data pooled across the 3 trials is reported below in Figure 3.1. Whilst the point estimate is in favour of Mepilex Border Sacrum, the difference is not statistically significant (RR 0.51 [95% CI 0.22 to 1.18] p=0.12).

Figure 3.1: Pooled analysis: Number of patients who developed pressure ulcers (Mepilex Border Sacrum vs. Standard Care)



When data from Santamaria 2015a were also considered, the difference between Mepilex Border Sacrum and placebo becomes statistically significant based on the fixed effects analysis (RR: 0.42 [95% CI 0.20 to 0.86], p=0.02) however the difference is not significant based on the random effects model (RR: 0.45 [95% CI: 0.20 to 1.04], p=0.06).

Figure 3.2: Pooled analysis Number of patients who developed pressure ulcers- sensitivity analysis including Santamaria 2015a (Mepilex Border Sacrum vs. Standard Care): Fixed effects



Pooling the results of studies for other outcomes was not possible due to paucity of data.

3.9 Ongoing studies

Two ongoing studies within the scope of the decision problem have been identified by the EAC.

One was identified as a clinical trial record (NCT03442777). The objective of the study is to compare pressure ulcer incidence in 'at risk' hospitalised patients receiving foam dressings (plus standard care) with patients receiving standard care alone. 1,662 patients have been randomly assigned to 1 of 3 arms:

- Allevyn brand silicone adhesive multilayer foam dressings.
- Mepilex brand silicone adhesive multilayer foam dressings.
- Standard care.

The study, sponsored by the Belgium Health Care Knowledge Centre, commenced on February 8 2018. The study is estimated to complete on December 31 2019.

A study protocol was identified for a cluster-controlled trial of Allevyn Life Sacrum compared with Mepilex Border Sacrum (Gordon 2017). According to the protocol, the study commenced recruitment in February 2016 and was expected to end recruitment in August 2017. No further details associated with this study have been identified. The EAC has considered this an ongoing study.

4 Economic evidence

4.1 Published economic evidence

Throughout this Section, Mepilex Border is used as an overarching term for Mepilex Border Heel and Mepilex Border Sacrum unless otherwise specified.

Critique of the company's search strategy

Section 10.3 Appendix 3 of the company's submission contains a description of the company's search methodology for identifying economic evidence. The company undertook the search for economic evidence as part of the overall search for clinical evidence (consisting of a search of MEDLINE and Embase and a search of 2 internal company sources), with the addition of a search of the NHS Economic Evaluation Database (NHS EED). A critique of the company's overall search for clinical evidence is provided in Appendix A. As discussed in Section 3.1, the reported search methodology had some limitations which could potentially have impacted on search sensitivity. The additional search of NHS EED also had limitations which could potentially have impacted on search sensitivity.

The company's search strategy for NHS EED was not reported in full detail, but enough information was provided for the EAC to approximate a re-running of the search. The search retrieved 15 records. Of the 15 records, 2 were duplicates of records already retrieved and screened as part of the EAC *de novo* searches, leaving 13 unique additional records from the re-run NHS EED searches for assessment. A full critique of the company's search methods for economic evidence and details of the re-run company's NHS EED search are provided in Appendix H.

The *de novo* searches carried out by the EAC (reported in Appendix A) were not restricted by study design and were prospectively designed to retrieve both clinical and economic evidence. No additional *de novo* EAC search for economic evidence was therefore conducted.

Critique of the company's study selection

Company's study selection

The company undertook the search for economic evidence as part of the overall search for clinical evidence, and adopted selection criteria in line with clinical evidence with the exception of outcomes (a critique of the selection criteria is described in Section 3.2). They state studies were included that referred to economic outcomes, if they calculated or estimated a cost saving or consequence from the use of Mepilex Border products including combination of Mepilex Border product with another Mepilex prophylactic dressing (such as Mepilex non-adhesive dressings with Tubifast bandages e.g. Mepilex Heel, as seen in the Section 3.2). It is not clear from this whether specific study designs were considered.

EAC's study selection

The selection criteria adopted by the EAC to select relevant economic studies are summarised in Table 4.1. These are consistent with the scope.

Table 4.1: Selection criteria adopted by the EAC for economic study selection

	Inclusion criteria	Exclusion criteria
Population	Patients at risk or at high risk of pressure ulcers in acute care settings	Patients in other care settings (e.g. aged care setting)
Intervention	Mepilex Border Heel dressing, Mepilex Border Sacrum dressing and Mepilex Border dressing (when applied to the heel or sacrum) used as an adjunct to standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers	Other Mepilex dressings
Comparators	Standard NHS clinical practice for patients considered 'at risk' or 'at high risk' of pressure ulcers. This may involve a combination of: • Risk assessment with a validated scale • Skin assessment • Frequent repositioning (at least 6 hourly in people considered to be at risk and 4 hourly in people considered to be at high risk) • Pressure redistribution using devices such as high-specification foam mattress or pressure redistributing cushions. • Other dressings or skin applications to prevent pressure ulcers • Information • Barrier cream (specified situations)	
Outcomes	Not specified to maximise sensitivity	
Study design	Health economic studies (Mepilex Border v. comparator) • Cost-effectiveness • Cost-utility • Cost-benefit • Cost-minimisation • Cost-consequence	Non-comparative cost analyses including cost of illness studies. Clinical studies reporting on cost of treatment in the discussion only without more formal analyses.
Limits	No language restrictions A date limit of 2001 was applied to the search	Studies published before 2001

The EAC applied the selection criteria listed in Table 4.1 to the literature search reported in Section 3.1

Included and excluded studies

Company's selected studies

The company identified 6 studies that met its selection criteria (Section 8.3.1, Submission) from its search. One additional poster (Fimiani 2017) was identified by the company after its search and was also included bringing the

total to 7 included studies. It is not clear from the submission how this additional study was identified. These studies are summarised in Table 4.2. The EAC could not fully replicate the company's search methods so could not confirm whether all studies identified by the company's searches were included or excluded appropriately. However, no additional studies were identified by the EAC.

Table 4.2: Summary of company's included economic studies

Study and setting	Design	Population	Intervention	Comparator	EAC's judgement on inclusion
(Santamaria et al. 2015), Australia	Cost benefit analysis based on a RCT	Patients admitted to emergency department and ICU for critical illness or major trauma.	Mepilex Border Heel and Mepilex Border Sacrum	Standard care	The EAC agrees with inclusion of this study
(Santamaria and Santamaria 2014), Australia	Clinical study	Patients at high risk of pressure ulcer.	Mepilex Border Heel and Mepilex Border Sacrum	Standard care	The EAC agrees with inclusion of this study
(Kalowes et al. 2016), USA	Clinical study	Patients admitted to medical, surgical, trauma ICU or cardiac ICU.	Mepilex Border Sacrum	Standard care	The EAC excluded the study as it was not a heath economic study
(Padula 2017), USA	Retrospective observational cohort study	Patients hospitalised for at least 5 days in acute care.	5-layer sacral dressing	No head-to-head comparator. Used regression analysis to compare with standard care.	The EAC excluded this study on the basis of no head-to-head comparator
(Johnstone and McGown 2013b), Scotland	Clinical study	Patients admitted to critical care	Mepilex Border Sacrum	No comparator	The EAC excluded this study on the basis of no comparator
(Lientz 2013), USA	Clinical study	Patients admitted to critical care or ICU	Mepilex Border Sacrum	No comparator	The EAC excluded this study on the basis of no comparator
(Fimiani 2017), USA	Non-randomised comparative study	Patients admitted to hospital	Mepilex Border Sacrum	Allevyn Life Sacrum	The EAC excluded this study on the basis of wrong comparator

The company critically appraised all 7 included studies. The 4 studies the EAC judged to be out of scope are not discussed further in this report.

EAC's selected studies

Those records identified during the clinical searches (reported in Section 3.1) were sifted in addition to those identified through the re-run company's search of NHS EED. In total, 1,255 records were screened. Two studies met the EAC's inclusion criteria, as listed in the table above. A PRISMA diagram is presented in Appendix H.

Overview of methodologies of all included economic studies

One included study, (Santamaria et al. 2015), presents a cost-benefit analysis based on a RCT which was undertaken in the emergency department and ICU of a large teaching hospital in Australia comparing Mepilex Border Sacrum with standard care. Cost data were collected during the trial based on a total of 313 patients (intervention n = 161, control n = 152) on hospital resources and time used to provide pressure ulcer care. Marginal costs associated with the use of dressings in the intervention group were calculated. Pressure ulcer treatment costs were calculated specific to the ulcer stage.

The second included study, (Santamaria and Santamaria 2014), presents a budget impact estimate of using Mepilex Border dressings to prevent hospital acquired pressure ulcers in Australia, based on the (Santamaria et al. 2015) cost benefit analysis discussed in the paragraph above. An estimate of the number of patients at high risk of pressure ulcer in Australia was combined with the costs calculated in (Santamaria et al. 2015).

Table 4.3: Results of EAC's included economic studies

Study	Costs	Patient outcome	Results
(Santamaria et al. 2015), Australia	The following costs were included: • Consumable costs • Labour costs • Pressure ulcer treatment costs	No additional outcomes reported.	Total average cost intervention $71 Total average cost control $145 Incremental average cost (calculated) -$74
(Santamaria and Santamaria 2014), Australia	The following costs were included: • Consumable costs • Pressure ulcer treatment costs	No additional outcomes reported.	Total average cost intervention $67 Total average cost control $142 Incremental average cost (calculated) -$75 Total savings for Australia $34,803,641

Overview and critique of the company's critical appraisal for each study

The company critically appraised all of its included economic studies in Section 8.2.2 of the submission using the Drummond checklist (Drummond and Jefferson 1996) which the EAC deemed appropriate. The EAC checked the critical appraisal of the 2 studies which it deemed appropriate for inclusion.

One included study (Santamaria et al. 2015), was considered to be well conducted and reported. However, given that the cost information is specific to an Australian health care system, its external validity to the decision problem and the NHS is fairly poor. However, resource units are presented for the application of the dressing which is useful.

The second included study (Santamaria and Santamaria 2014), is based on the cost benefit analysis conducted in Santamaria 2015b so does not contribute anything further to the decision problem.

Does the company's review of economic evidence draw conclusions from the data available?

The company drew no conclusion from its included cost-effectiveness studies. The EAC concludes that based upon its included studies, Mepilex Border may be cost saving compared with standard care. However, both studies were based on a single trial conducted in Australia with Australian costs applied. Therefore, there is insufficient evidence to draw any robust conclusions for the NHS. Consequently, the EAC deems the company's decision to produce a *de novo* cost analysis to be appropriate.

4.2 Company de novo cost analysis

A *de novo* cost model was created by the company which was appropriate given the lack of UK-based economic evidence available. The submitted model was largely based on 1 RCT (Santamaria et al. 2015a) and cost-benefit analysis (Santamaria et al. 2015) included within the cost-effectiveness review. The structure of the model is described below.

4.2.1 PICO analysis

Patients

The company stated that the patient groups included in the analysis are patients at risk or at high risk of pressure ulcers in acute care settings. This is consistent with the scope issued by NICE. However, the trial used for the primary outcome of pressure ulcer incidence was based on a majority of high risk patients.

Technology

The technology considered in the model was Mepilex Border Sacrum and Mepilex Border Heel dressings which is consistent with the scope. However, the trial used for the primary outcome of pressure ulcer incidence used the 3-layer Mepilex Heel with Tubifast rather than the 5-layer Mepilex Border Heel dressing (Santamaria et al. 2015a). The Mepilex Border Sacrum dressing was consistent between both the trial and the scope.

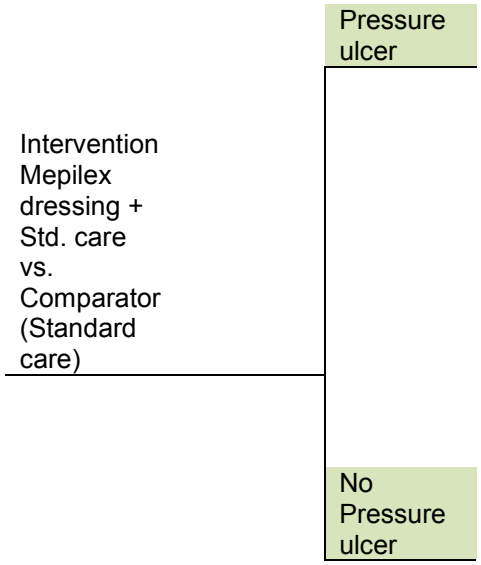
Comparator(s)

The comparator used in the model was standard care which is consistent with the scope. However, the baseline rate of pressure ulcers for the comparator was taken from a RCT based in Australia (Santamaria et al. 2015a), and standard care within the trial was not well defined, so it is not clear whether this was consistent with standard care in the NHS. Further, the baseline rate of pressure ulcer did not appear to be consistent with the rate of pressure ulcer in the current NHS. This is detailed in Section 4.2.5.

4.2.2 Model structure

The model structure submitted by the company was a very simple decision tree produced in Microsoft Excel utilising the MTEP template provided by NICE. Two possible outcomes were included – patients could either acquire a pressure ulcer or not acquire one. The diagram of the model structure as presented by the company in Section 9.1.4 of the submission is presented in Figure 4.1 below and was deemed to accurately reflect potential changes to the patient pathway with Mepilex Border dressings.

Figure 4.1: Diagram of model structure



The structure was justified by the company as reflecting the primary outcome which was the focus of published analyses, and that all costs and QoL impacts would stem from this outcome. Quality of life was not considered as an outcome within the analysis. The EAC agrees that the structure appropriately captures the patient pathway and potential changes to this by using Mepilex Border dressings.

The model took a decision tree approach, hence time was not explicitly modelled. Rather, the model time horizon was the duration for which the resource use associated with the treatment of pressure ulcers occurs. The economic analysis undertaken for the NICE clinical guideline on pressure ulcers reports that even stage 4 pressure ulcers are expected to heal within 155 days (National Institute for Health and Care Excellence 2014b). Therefore, the time horizon of less than 1 year used by the company was deemed to be appropriate. Consequently, discounting of future costs (and benefits) was not required.

The EAC critically appraised the model using the (Drummond and Jefferson 1996) checklist. The completed appraisal checklist is reported in Appendix I.

The EAC independently replicated the company's calculations in order to check their accuracy. An error was identified in the company's base case results as calculated in its model relating to the nurse time used within the model. Rather than applying the duration of nurse time for the time that patients were using Mepilex Border dressings, the cost was applied over a full year. As such, the cost of nurse time was overstated. Correction of this error in the EAC model increased the cost savings with Mepilex Border dressings.

4.2.3 Critique of assumptions

The company listed the following assumptions in its submission:

- *Pressure ulcer rate reductions in the trial data from Australia and the USA are likely to be replicated in the UK due to pressure ulcer care guidelines being international and wound care stages 1-4 being standardised.* The EAC judges that the baseline rate of pressure ulcer could have a significant impact on the scope for improvement and therefore the reduction in incidence of pressure ulcer. It is not clear whether the company attempted to assess the comparability of pressure ulcer rates between the UK and Australia and the US. Further, the pressure ulcer incidence rate from the main trial (Santamaria et al. 2015a) used for pressure ulcer incidence in the model appears to be much higher than would be expected in the UK, this is discussed in more detail in Section 4.2.5. It is also not clear what standard care (for pressure ulcer prevention) consisted of in this trial. Therefore, it is not

possible to assess how comparable this was to standard care in the UK.

- *Pressure ulcer rate reduction in the trial is likely to be achieved in a real world setting as nurses will be familiar with pressure ulcer protocols and products and the relevant trials were conducted in close to real-world settings.* The EAC agrees that nurses will be familiar with pressure ulcer protocols. However, compliance with using the dressings could differ in the real world.

- *Time resource for nurse application of dressing will be similar to the RCT.* The EAC agrees that this is likely to be similar in real world practice, and the majority of experts estimated a dressing change to take a few minutes, which is in line with the figure reported in the trial used for the company base case.

- *Costs of pressure ulcer in the UK are known and are taken from the latest and recently published modelling tool from NHS improvement.* Although the modelling tool is a good source, the costs used in the tool are from a much older paper (Bennett et al. 2004) and inflated. Other, more up-to-date sources are available. The costs reported are also for all types of pressure ulcer, not just heel and sacral, which reduces their generalisability to the decision problem. However, the EAC did not identify any robust cost sources reporting the cost of pressure ulcers (by stage) at specific locations.

- *Results are comparable for variants of dressings in the RCT and products that are the subject of the submission.* The RCT by (Santamaria et al. 2015) used Mepilex Heel (3-layer dressing) with tubular bandage to secure it rather than Mepilex Border Heel. The *de novo* analysis uses the pricing of Mepilex Border Heel (which is more expensive). The EAC considered Mepilex Heel to be out of scope because it is a different dressing to the 1 under consideration. The company stated in correspondence with the EAC that the Mepilex Border Heel dressing is likely to be as effective, or more effective, than the Mepilex Heel dressing but that there are no studies on which to base this. Although this is more likely to be a conservative assumption, the EAC considers that another source could have been used for the efficacy data which only assessed the relevant interventions.

- *Agenda for change banding costs in the economic model template are appropriate for the model, price base year is assumed to be 2016-17 which is the same price base year for other data and wound care nurses are typically band 6.* The EAC notes that the salaries used in the model

are from 2015 and, therefore, not consistent with the price base year in the model. It is unclear from the company submission whether the costs have been inflated. Cost year aside, the EAC deems these costs to be appropriate.

The EAC has identified the following additional assumptions made by the company relating to the model:

- The company assumes that single-site data from Australia are generalisable to the current NHS (Santamaria et al. 2015). This assumption of generalisability applied to baseline incidence rate of pressure ulcer and that the patients and standard care included in the study are representative of those defined in the scope.

- No implementation or training was costed as part of the company's cost analysis. The company stated in correspondence with the EAC that training would be provided free of charge by the company, and would take a maximum of 1 hour. Therefore, given staff time would be negligible in the longer term (as more patients receive the dressings), the EAC deemed the exclusion of this appropriate.

- Adverse events were also assumed not to occur in the company's model. However, very little evidence of adverse events was identified by the EAC, and those adverse events that were identified have very little or no cost associated with them. Therefore, the EAC considers the exclusion of adverse events to be appropriate.

Overall the EAC considered the company's model to capture the key aspects of the intervention, and that the model structure used was appropriate. The key issues with the model related to the data used to populate the model and how well the data generalise to the decision problem in the scope. This is discussed further under Sections 4.2.5 and 4.2.6.

4.2.4 Summary of the base case

Results from the company's economic model were provided in Section 9.5 of the submission. These results are reported in Table 4.4. The company presented its sensitivity and scenario analysis in Sections 9.5.6 to 9.5.11 of its submission.

Table 4.4: Company's base case results

	Mepilex	Standard care	Incremental cost per patient
Dressings	£38	£0	£38
Staffing costs	£73	£0	£73
Pressure ulcer treatment costs	£120	£408	-£288
Total			**-£177**

4.2.5 Clinical parameters and variables

A description and critique of the clinical parameters included in the company's model is now provided. Table 4.7 reports the parameters adopted in the EAC's model, with differences between the company and the EAC parameters highlighted.

The key clinical parameter in the model is the incidence of pressure ulcer with standard care and with standard care plus Mepilex Border dressings. For both the standard care and the Mepilex Border dressing arms, the company used pressure ulcer incidence reported in 1 RCT (Santamaria et al. 2015a). This RCT was conducted in a single centre in Australia. Therefore, the EAC considers that this incidence rate was inappropriately used in the standard care arm due to the potential lack of generalisability to the current NHS. Furthermore, standard care was not well described in the trial. Therefore, it is not possible to know how well this compares with standard care in the NHS. The EAC deemed a more appropriate method to be:

- Identification of the baseline incidence of pressure ulcer from a UK specific source to represent the incidence of pressure ulcer with standard care.

- Calculation of a relative risk of pressure ulcer from the trial and application of this to pressure ulcer incidence to calculate the incidence of pressure ulcer with Mepilex Border dressings.

To find a pressure ulcer incidence that is more generalisable to the NHS, the EAC conducted a pragmatic search for a pressure ulcer incidence (with standard care) in the UK with a date limit of 2012. The search strategy is detailed in Appendix J. The search also included terms to identify treatment costs of pressure ulcer since this was also considered to be a key parameter (discussed further in Section 4.2.6). A 2012 date limit was chosen because studies older than this were judged not to be representative of UK clinical practice today. The search aimed to restrict inclusion to only those studies set in the UK. It was supplemented by targeted searching of the grey literature and

inviting clinical experts to provide any information relating to useful sources of information (see correspondence log).

The aim of the search was to determine the incidence of pressure ulcer (with standard care) which could be combined with the trial data from the key RCTs to infer the pressure ulcer incidence in the Mepilex Border dressings arm. A total of 358 results identified via the search (of Medline) and, following screening of these and records identified from other sources, 2 records were judged to be of use.

The first of these, the NHS safety thermometer, provides data on prevalence and incidence of pressure ulcers in an acute care setting, as well as for specific ward types (NHS Improvement 2017-2018). Although a voluntary scheme, trusts are incentivised and most do participate. Data are collected through a point of care survey on a single day each month on 100% of patients. Data are collected on the number of patients with a pressure ulcer (new and old), which allows the calculation of prevalence, and of incidence over a 1 month period. The EAC deemed this to be the most useful source of pressure ulcer incidence as it is collected from a variety of UK NHS trusts so represents a good estimate of the average incidence of pressure ulcers in the NHS. Furthermore, incidence data are also available by ward type. This allowed the EAC to find an incidence rate specific to critical care units, which is more likely to be reflective of the population of interest from the scope i.e. at risk or high risk of pressure ulcer, and is aligned with the clinical studies included in Section 3.8. However, the EAC acknowledges that this source has the following limitations:

- Research has shown that the tool significantly under reports the incidence and prevalence of pressure ulcers, with 1 study estimating the sensitivity of the survey to be 48.2% (Smith et al. 2016), meaning that the incidence could be more than double that reported.

- There is a lack of guidance on what classification system to use to categorise pressure ulcers. Therefore, there may also be inconsistencies in reporting.

- Pressure ulcers occurring within 72 hours of admission are classified as ‘old’ and, therefore, will not be included in the incidence estimate. This could mean further under-reporting.

- Stage 1 pressure ulcers are not reported.

- Not all NHS trusts submit data to the tool, hence selection/reporting bias may result from self-selected sample of trusts included.

Average pressure ulcer incidence was calculated for data from February 2017 to February 2018 for new pressure ulcers in critical care and in all wards. The critical care incidence was calculated to be 1.96%, and the all wards incidence to be 0.78% (NHS Improvement 2017-2018).

The second useful study by Richardson et al. examined the effect of a bundle of interventions implemented in an attempt to reduce pressure ulcer incidence across 4 adult critical care units in 2 acute hospital sites in the UK (around 5,000 admissions per year) (Richardson et al. 2017). The incidence rate reported before the bundle intervention was introduced was 6.7%. However, the author acknowledged that this was high and, as such, this may not reflect a typical average rate for an NHS trust. Furthermore, this rate was reported between 2011 and 2012, before national drives to reduce pressure ulcers such as 'Stop the pressure' were implemented (described in Section 2.1.2). As such, the source may be outdated. After the intervention bundle was introduced, this rate reduced to 1.9%, which was measured in 2015. This is more likely to be representative of the NHS today because interventions introduced during the study were mainly around implementing best practice and training staff. However, alternating low pressure mattresses were also introduced, which may not be routinely used in all patients as part of standard care, so this rate is may be lower than the typical rate seen in an NHS trust.

Given the limitations and under reporting of the NHS safety thermometer, and the likely lower than average rate reported by Richardson et al, the EAC decided to adjust the NHS safety thermometer data to approximately account for the following:

1. The figure was inflated to account for the estimated sensitivity of the survey as reported by Smith et al. (Smith et al. 2016). The incidence rate of 1.96% as reported for critical care patients was inflated by 0.518 (1-0.482) to give an estimated incidence proportion of 4.07%. However, a limitation of this approach is that the Smith paper was not specific to an ICU population.

2. This figure was then deflated to account for only heel and sacral pressure ulcers, as the NHS safety thermometer data reports pressure ulcers on all locations of the body. Clark et al. was used to estimate the proportion of pressure ulcers that occur on the heel or sacrum, which gave a figure of 63.8% (Clark et al. 2017). Deflating the incidence rate by this proportion gave an overall pressure ulcer incidence in the heel and sacrum of 2.6%.

3. This value was then inflated by the estimated proportion of pressure ulcers that would be missed because they were classified as stage 1

and so not reported. Clark et al. report the prevalence of heel and sacral pressure ulcers split by stage in an audit undertaken in 8,365 patients located across 66 hospitals in Wales in 2015 (Clark et al. 2017). Approximately 31% of heel and sacral pressure ulcers were stage 1[4], so the 2.6% figure was inflated to account for these missed pressure ulcers to 3.8%. However, it should be noted that the study by Clark et al. was also not specific to an ICU population which is a limitation of the adjustment described under both points 2 and 3.

The pressure ulcer incidence (specific to heel and sacrum) of 3.8% is similar to the proportion reported by the other 2 key RCTs found in the clinical searches (Aloweni et al. 2017, Kalowes et al. 2016). The rates reported by Kalowes and Aloweni were 4% and 5% respectively for the control (standard care) arm. Although these trials were conducted in Singapore and the US, they both reported a detailed description of the protocols used in the standard care arm. Both were found to have similar protocols for pressure ulcer prevention as used in the UK for standard care, according to NICE guidelines (National Institute for Health and Care Excellence). Specifically Kalowes (Kalowes et al. 2016) used the SSKIN bundle, which was named by 3 of the experts surveyed by the EAC as the approach followed for standard care (see correspondence log).

The 3.8% estimate of pressure ulcer incidence with standard care was used in the EAC base case with alternative rates of 2.5% and 46% explored in sensitivity analysis as per high and low values from included comparative studies as detailed in Section 3.6.2 (noting that none of these studies were set in the NHS). It is recognised that there is likely to be heterogeneity within the NHS around pressure ulcer incidence with standard care. Thus, the wide range of values considered reflects this. A threshold analysis was also conducted around the standard care incidence rate in order to explore the likely lower limit for baseline incidence needed for Mepilex Border dressings to be cost saving.

The pressure ulcer incidence with Mepilex Border dressings in the company model was taken from Santamaria 2015 (Santamaria et al. 2015a). The EAC notes that this is the only RCT examining both sacrum and heel dressings, although the heel dressing is not a Mepilex Border dressing but the 3-layer Mepilex dressing combined with Tubifast for attachment to the foot. Rather than use 1 trial, the EAC pooled the results of the 3 included RCTs in relation to sacrum pressure ulcer incidence which gave a relative risk estimate of 0.51 [CI 0.22 to 1.18], as described in Section 3.8, which was used in the EAC base case. The second meta-analysis reported in Section 3.8 (using the fixed effects

[4] 70 stage 1 sacrum pressure ulcers, 44 stage 1 heel pressure ulcers out of a total of 371 pressure ulcers (excluding unknown stage pressure ulcers)

model) was considered within a scenario analysis in the model (RR: 0.42 [95% CI 0.20 to 0.86]).

Data are limited in that no RCTs reporting on Mepilex Border Heel were identified and included. One non-randomised comparative study set in Australia reported an incidence of 14 (9.2%) pressure ulcer in the standard care arm and 0 (0%) incidence of pressure ulcer with Mepilex Border Heel (Santamaria et al. 2015b). This suggests that the trend towards a reduction in pressure ulcer holds for the Mepilex Border Heel. However, this conclusion is limited by the paucity of data and internal/external validity of the single study (described in Table 3.4)

4.2.6 Resource identification, measurement and valuation

Pressure ulcer treatment costs

The company details in its submission that the costs for treatment of pressure ulcer were taken from the NHS pressure ulcer productivity calculator (NHS Improvement 2018a), which was originally developed and published by the Department of Health in 2010. The tool has recently been updated with costs inflated to a 2016/17 price year. The company states that the tool uses costs from a paper by Dealey et al. which are then inflated to current prices (Dealey et al. 2012). However, from a review of the tool it appears that the costs reported in the tool are actually from Bennett 2004 (Bennett et al. 2004) and inflated using PSSRU inflation indices (Personal Social Services Research Unit (PSSRU) 2017). The EAC was able to reconcile the values in the tool using these original sources.

Costs were reported by stage of pressure ulcer in the company submission. Since the structure of the model did not allow for incidence of pressure ulcer by stage, the company appropriately weighted the cost of pressure ulcer by the number of pressure ulcers in each stage for the intervention and comparator arms from the Santamaria cost-benefit analysis (Santamaria et al. 2015). This led to a higher cost of pressure ulcer in the intervention arm due to a higher proportion of stage 2 (than stage 1) pressure ulcers in the Mepilex Border dressings arm. However, the sample of pressure ulcer used for the weighting was small: n=7 in the Mepilex arm and n=27 in the standard care arm. Therefore, there is much uncertainty in this weighting.

As discussed in the Section 4.2.5, the EAC undertook a pragmatic search to find a UK cost for the treatment of pressure ulcer in an attempt to find a more recent source. Four records were included at full text stage. The paper by Dealey was considered to be the best source as the study costed the treatment of pressure ulcers using a bottom-up methodology based on resources required to deliver protocols of care reflecting good clinical practice with prices reflecting

the costs to the health and social care system in the UK (Dealey et al. 2012). The paper also reported the cost for different stages of pressure ulcer. Two of the other records (Marsden et al. 2015, National Institute for Health and Care Excellence (NICE) 2014) used costs from Dealey, and the final record (Castelli et al. 2015), reported costs specific to hip fracture patients. Therefore this was not considered to be generalisable.

The Dealey (Dealey et al. 2012) costs were reported at a 2011 price year, so were inflated by the EAC using PSSRU inflation indices (Personal Social Services Research Unit (PSSRU) 2017) to a 2016/17 price point to use within the updated company model. These costs are shown in Table 4.5. In order to weight the costs by the number of pressure ulcers in each stage the EAC gathered data on the stage of pressure ulcer reported in all of its included studies. However, due to the low event numbers it did not provide a meaningful distribution, and involved making assumptions around the heterogeneity in reporting and classification of stages between studies which may not be defensible. Consequently the EAC explored other potential sources reporting on the distribution of pressure ulcer by stage which are shown in Table 4.5. All sources and their limitations are discussed in Section 4.2.6.

Table 4.5: Cost of pressure ulcer treatment as calculated by the EAC

Stage of pressure ulcer	Cost from Dealey (inflated)	Weighting from NHS safety thermometer (NHS Improvement 2017-2018)*	Weighting from Richardson 2017 (Richardson et al. 2017) (2015 year)	Weighting from NHS Pressure ulcer productivity calculator (NHS Improvement 2018a)	Clark 2017 (Clark et al. 2017)**
1	£1,299	0.33	0.11	0.35	0.33
2	£5,608	0.54	0.86	0.41	0.44
3	£9,675	0.11	0.04	0.13	0.14
4	£15,097	0.02	0.00	0.11	0.09
Pressure ulcer treatment cost	-	£4,823	£5,352	£5,672	£5,609

*Note these figures have been adjusted to account for stage 1 pressure ulcers which are not reported by NHS safety thermometer, using Clark 2017 (Clark et al. 2017).
** Note this study reports prevalence not incidence. Unstageable and unknown pressure ulcers have been excluded for the purpose of calculating the distribution. Deep tissue injuries have been classified as stage 4.

The cost of pressure ulcer weighted by the NHS safety thermometer data was used in the EAC base case given this is a large and recent source of data that is specific to an ICU population within the NHS. Using data on an ICU population is aligned with participants in the clinical studies (reported in Section 3) on which the relative risk of pressure ulcer with Mepilex Border dressings are based. The weightings for the distribution of pressure ulcer by stage was

adjusted for the missed stage 1 pressure ulcers using the proportion of stage 1 pressure ulcers reported by Clark et al. 2017 (Clark et al. 2017). However, it should be noted that the Clark study is not specific to an ICU population.

Given the limited clinical data on stage of pressure ulcer from the Mepilex trials, the EAC assumed that the reduction in pressure ulcer incidence with Mepilex was uniform across all stages of pressure ulcer (see Section 3.6). This assumption was explored in sensitivity analysis.

Dressing changes

The number of dressing changes in the company's model was taken from the Santamaria trial (Santamaria et al. 2015) (ICU patients, Australia), as detailed in Table C5 of the submission. The frequency of sacral and heel dressings were reported as 274 and 465 over 219 patients for the duration of the study. The company used these figures to calculate 2 sacral dressing changes (274/219 = 1.25, rounded up to 2), and 2 heel dressing changes per heel ([465/219]/2 = 1.06, rounded up to 2). Therefore, the cost of 2 sacral dressings and 4 heel dressings was applied in the company's model base case, along with the cost associated with the nurse time for 6 dressing changes. The mean LOS in ICU reported in the study was 3.8 days. Clinical experts surveyed by the EAC suggested that the dressing should be changed every 3 days, or more often if soiled or dislodged. Therefore, 2 dressing changes over this length of stay seems reasonable (see correspondence log).

Further evidence relating to dressing changes was available. The additional RCT identified by the EAC (high risk patients in medical/surgical wards, Australia) reported that the median time sacral dressings remained in place was 2 days (Walker et al. 2017). The study did not assess heel dressings. Given the reported median LoS was 6 days, the EAC calculated an estimated number of dressings per patient of 3. The paper also reported that 150 dressings were purchased for the study for an intervention group of 39 people, which calculated as 3.8 dressings per person if they were all used. However this was not reported.

Two non-comparative observational studies that were conducted in the UK were identified in the review. The first of which, (Johnstone and McGown 2013b) (ICU patients), reported an average of 4 Mepilex Border Sacrum dressings per patient used over a median LoS of 9 days. The second study, (Bateman and Roberts 2013) (patients referred to wound care service), did not report the number of dressings used but did report that dressings were changed at least every 72 hours, unless soiled or dislodged. Neither study assessed heel dressings.

Another study (Padula 2017) (patients in any acute care ward), conducted in the US reported an average of 1.5 Mepilex Border Sacrum dressings used over an average LoS of 7 days.

Given that the paper by Johnstone et al. was the only UK study to report the number of dressings used, this was used by the EAC in the base case (Johnstone and McGown 2013b). Therefore, a conservative value of 4 dressings per patient for the sacrum was used in the model base case. Lower values were explored in sensitivity analysis reflecting the alternative sources reporting few dressing changes. It was noted by the EAC that the mean treatment duration (9 days) in this study is longer than that typically seen in a UK ICU, where the mean LoS is reported to be 4.8 days (Intensive care national audit & research centre (icnarc) 2018). This discrepancy may reflect the difference between patients eligible for Mepilex Border dressings and the ICU population more generally (i.e. those with a very short length of stay may not benefit from the dressing).

An assumption was made for Mepilex Border Heel dressings because these were not assessed in the Johnstone and McGown study. A slightly lower value of 3 dressings per heel was used in the base case (6 dressings in total per patient) based on information from the Santamaria trial which reported fewer dressings being used on heels than on the sacrum (Santamaria et al. 2015).

Staff costs

The company costed nurse time for each dressing change in its model. Costs of nurse time were calculated from the agenda for change pay scale salaries taking into account a full time working week, adjustment for national insurance, superannuation, annual leave allowance and contribution to overheads for a band 6 nurse. This resulted in a cost per minute of £0.51 being applied. A total of 12 minutes was allowed for dressing changes per patient (2 minutes per dressing change). However, the total value was then multiplied by 12 to give an annual estimate. The EAC did not consider this to be appropriate given that this is inconsistent with the timeframe used for other parameters in the model such as pressure ulcer incidence and number of dressing changes which are based on trial data and, therefore, are over a number of days rather than a full year. Therefore, the EAC calculated nurse costs using the total number of minutes for dressing change multiplied by the cost per minute of nurse time.

It was also noted by the EAC that nurse salaries were from 2015 so were slightly outdated, with more recent 2017 pay scales having increased (NHS Employers 2017). The EAC updated the costs to those reported by PSSRU 2017 which negates the need for adjustment for national insurance etc., using the cost per working hour. There was heterogeneity in clinical expert responses when

surveyed by the EAC around which grade of nurse would typically change a dressing. Of the experts, 3 suggested band 5 and above, and 2 suggested any band nurse (correspondence log). The EAC used the cost of a band 5 nurse in its base case which gave a value of £0.62 per minute. An average of all bands was explored in sensitivity analysis (£0.83).

The company based the estimated time taken per dressing change on the Santamaria 2015 trial (Santamaria et al. 2015). Clinical experts suggested that a dressing change would take a few minutes. Therefore, the EAC deemed this estimate to be appropriate and also applied an estimate of 2 minutes per dressing change in its base case. It should be noted that the analysis does not include any additional time added for peeling back the dressing to check the skin for patients receiving Mepilex Border dressings. However, clinical experts advised the EAC that this takes less than a minute or a few seconds and is part of routine care (correspondence log). Therefore, the EAC judged that this additional time cost is likely to be negligible.

Technology and comparator costs

The company used a cost of £0 for the comparator which was deemed to be appropriate given that the dressing is to be used as an adjunct to standard care and, therefore, the costs of standard care would be equivalent between the 2 arms of the model.

The company used a cost of £4.44 for the Mepilex Border Sacrum dressing (16 x 20cm) and £7.21 for the Mepilex Border Heel dressing (22 x 23 cm) (both ex VAT). These costs are consistent with the prices supplied by the company and with prices identified from NHS supply chain. The EAC notes that different sizes for the Mepilex Border Sacrum dressing are available with the larger version (22 x 25cm) costing £7.26 per unit, and the smaller version (15 x 15cm) costing £3.06 per unit. The Mepilex Border Heel dressing is also available in a smaller size (18.5 x 24cm), costing £6.47 per unit. The company supplied the relative sales figures of each of the dressings to the EAC, which allowed the EAC to calculate a weighted average cost per unit. This is shown in Table 4.6. The EAC therefore used a cost of £6.50 for the heel dressing and £4.63 for the sacrum dressing.

Table 4.6: Treatment costs

Dressing type and size	Unit price (ex VAT)	Percentage of sales
Mepilex Border Heel 22cm x 23cm	£7.21	4%
Mepilex Border Heel 18.5cm x 24cm	£6.47	96%
Weighted average cost	£6.50	
Mepilex Border Sacrum 15cm x 15cm	£3.06	31%
Mepilex Border Sacrum 16cm x 20cm	£4.44	47%
Mepilex Border Sacrum 22cm x 25cm	£7.26	22%
Weighted average cost	£4.63	

4.2.7 Sensitivity analysis

A 'best case' and 'worst case' scenario were presented in the company model alongside the base case results which examined the impact of varying the incidence of pressure ulcer with Mepilex Border dressings. No other parameters were varied as part of the best case and worst case scenarios. However, this was as per the MTEP template. The pressure ulcer incidence with Mepilex Border dressings was varied between 0% as a best case scenario and 6.2% as a worst case scenario. This range was not justified by the company in its submission, but the submission did note that 6.2% was used because this was double the base case value of 3.1%. The EAC deemed this upper value to be high enough to give a conservative estimate.

The company chose not to vary the incidence of pressure ulcer in the standard care arm and justified this by stating that this rate was assumed typical so was kept constant in the model. The EAC did not deem this justification to be sufficient, particularly given that it is a key driver of the results of the analysis.

A tornado diagram was presented in the company model which showed the key drivers of the model to be the incidence of pressure ulcer in the Mepilex Border dressings arm (standard care arm was not varied), and pressure ulcer treatment costs. The company did not vary the staffing costs to change the dressing in the tornado diagram, because the template did not process the input data. The EAC varied this parameter to explore any uncertainty in this input.

None of the inputs varied individually by the company in its deterministic sensitivity analysis changed the direction of the results.

4.2.8 Scenario analysis

The company undertook some threshold analyses around the incidence of pressure ulcer, and the cost of consumables, as well as 2 scenario analyses which explored different Mepilex Border dressing pricing and different trial data.

The first scenario presented by the company used pricing for Mepilex Heel + Tubifast instead of the Mepilex Heel Border pricing used in the company base case. This gave a lower overall cost for the Mepilex Border dressings of £28.24 (4 heel dressings plus 4 Tubifast and 2 sacrum dressings) rather than £37.73 (4 heel dressings and 2 sacrum dressings) used in the company base case. This generated a cost saving of £187 per patient. However, the EAC deemed this analysis to be outside the scope due to Mepilex Heel, which is not the intervention of interest, being used.

The second scenario presented by the company used trial data from Kalowes (Kalowes et al. 2016) for the incidence of pressure ulcer rather than Santamaria (Santamaria et al. 2015a) which was used in the base case. Pressure ulcer incidence of 0.7% was used for the dressings arm compared with 5.9% in the standard care arm. The company also altered the costs of the intervention due to the Kalowes study only assessing Mepilex Border Sacrum dressings. An assumption was made that 3 sacrum dressings were used per patient, which was presumably based on information provided in the study that dressings were replaced every 3 days unless soiled or dislodged, with an average LoS in ICU of 8 days in the dressings arm. However, the company did not report or justify this. The associated nurse time was also updated to 6 minutes in line with the 3 dressing changes. The treatment costs of pressure ulcer were also updated, presumably for a different weighting for the stage of pressure ulcer, although it is not clear how the company calculated these new values as they do not appear to match the EAC calculations based on the Kalowes trial report and the company did not provide any detail on this analysis in the submission. The company appears to have classified unstaged and deep tissue injury pressure ulcers from the trial as stage 1 pressure ulcers for the weightings. The EAC considers that deep tissue injuries at the least should be classified as stage 4 ulcers as they are more severe (National Pressure Ulcer Advisory Panel 2014b). The company used a cost of pressure ulcer treatment in the Mepilex Border dressings arm of £2,000, and in the standard care arm of £4,571. However, assuming deep tissue injury and unstaged pressure ulcers could be categorised at stage 4 (cost unavailable for unstaged and deep tissue injury) this would give costs for the treatment of pressure ulcer of £16,232 in the Mepilex Border dressings arm and £10,826 in the standard care arm. The result of the company analysis was a cost saving per patient of £206. Using the updated weighted costs actually increased the cost savings to £475 per patient due to the increased magnitude of the pressure ulcer treatment costs.

The EAC has undertaken additional analysis of parameters and also undertaken probabilistic sensitivity analysis (PSA) as reported in Section 4.4.

4.2.9 Table of full EAC revisions to the company's model

As described in Sections 4.2.5 and 4.2.6, the EAC disagreed with some of the input parameters and assumptions used by the company within its *de novo* cost analysis. The EAC updated a number of the input parameters. Table 4.7 provides a summary of the inputs used by both the company and the EAC.

Table 4.7: EAC revisions to the company's model

Parameter	Company base-case	Company source	EAC value	EAC source
Incidence of pressure ulcer – standard care	13.1%	(Santamaria et al. 2015a)	3.8%	NHS safety thermometer data (NHS Improvement 2017-2018) for ICU adjusted to account for poor sensitivity (Smith et al. 2016), missed stage 1 pressure ulcers and only heel and sacrum ulcers (Clark et al. 2017). (Section 4.2.5)
Incidence of pressure ulcer – Mepilex Border dressings	3.1%	(Santamaria et al. 2015a)	1.9%	Combined standard care pressure ulcer incidence with pooled relative risk calculated by EAC (Section 3.8)
Cost of pressure ulcer treatment – standard care	£3,111	NHS pressure ulcer treatment productivity calculator (NHS Improvement 2018a) weighted by stages from (Santamaria et al. 2015a)	£4,823	Costs from Dealey 2012 (Dealey et al. 2012). Weighted by NHS safety thermometer data (NHS Improvement 2017-2018), adjusted for stage 1 pressure ulcers (Clark et al. 2017) (Section 4.2.6)
Cost of pressure ulcer treatment – Mepilex Border dressings	£3,858	NHS pressure ulcer treatment productivity calculator (NHS Improvement 2018a) weighted by stages from (Santamaria et al. 2015a)	£4,823	Costs from Dealey 2012 (Dealey et al. 2012). Weighted by NHS safety thermometer data (NHS Improvement 2017-2018), adjusted for stage 1 pressure ulcers (Clark et al. 2017) (Section 4.2.6)
Total number of Mepilex Border Sacrum dressings per patient	2	(Santamaria et al. 2015)	4	(Johnstone and McGown 2013b)
Total number of Mepilex Border Heel dressings per patient	4	(Santamaria et al. 2015)	6	Assumption based on (Johnstone and McGown 2013b) and (Santamaria et al. 2015)
Cost of nurse time per minute	£0.51	NHS Agenda for change pay bands 2015, band 6 nurse cost used, adjusted for national insurance, superannuation, annual leave, overheads and full time working hours.	£0.62	Band 5 nurse cost (Personal Social Services Research Unit (PSSRU) 2017), validated by clinical experts.
Total number of minutes allowed for all dressing changes per patient	12 minutes	2 minutes per dressing change for 6 dressing (2 sacrum, 4 heel) (Santamaria et al. 2015)	20 minutes	2 minutes per dressing change (10 dressings, 4 sacrum, 6 heel) (Santamaria et al. 2015). Validated by clinical experts

4.3 Interpretation of economic evidence

The company compared its analysis and results with the published NICE MIB (National Institute for Health and Care Excellence 2017) reporting that the cost savings were approximately 4 times that calculated in the MIB. The MIB converted the marginal intervention cost and the marginal saving on pressure ulcer treatment from Australian dollars to UK pounds to work out a cost saving figure of £43 based on the Santamaria cost-benefit analysis (Santamaria et al. 2015). The company argue that pressure ulcer costs reported by Santamaria are much lower than in the UK which is why the cost saving in the MIB is much lower. The EAC would deem this statement accurate given the cost per day of pressure ulcer treatment reported in Santamaria ranged between $43 and $73, whereas the cost per day of pressure ulcer treatment in the UK is estimated to be between £43 and £374 per day (National Institute for Health and Care Excellence 2017). However, the pressure ulcer incidence in standard care in the Santamaria trial is unlikely to be representative of the UK, therefore limiting the study's usefulness for comparison. The company did not compare the cost savings with any other study, although no UK based studies were identified by the EAC against which to compare.

The company identified that the use of a single site unblinded RCT conducted in Australia was a weakness of the analysis, but did note that pressure ulcer prevention in the acute setting is well standardised internationally. However, the EAC judges that it is not possible to know whether standard care prevention of pressure ulcers in the study is generalisable with UK practice because the study did not give any details on how standard care was carried out.

The company also identified that the key RCT (Santamaria et al. 2015a) uses Mepilex Heel rather than Mepilex Border Heel, which is a limitation. However, the company added that the *de novo* analysis is likely to be conservative because the Mepilex Border Heel dressing is expected to result in improved performance compared with the Mepilex Heel dressing. The EAC notes that there is very little evidence for the heel dressings in general, although evidence so far suggests they may be beneficial (reported in Table 3.7).

The company notes that results may not be transferable to a paediatric population because there are no trial data to prove efficacy and, similarly, the use of the dressings in a community setting is also uncertain due to lack of RCT data. The company also suggests that a trial in a UK setting would probably be unnecessary due to likely transferability of clinical practice. The EAC judges that there are limitations in generalising the results to settings outside of critical care or an emergency department (where (Santamaria et al. 2015a) was set). This is discussed further in Section 7.

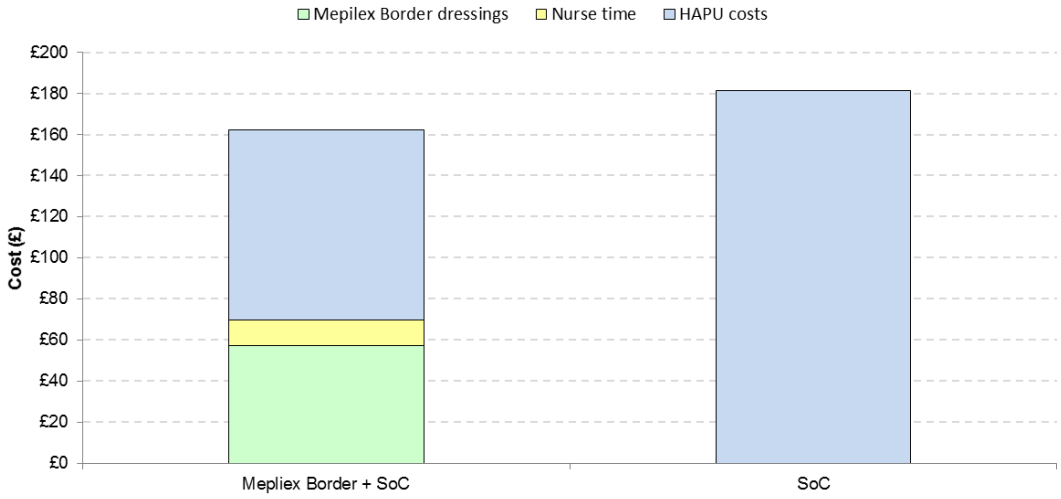
4.4 Results of EAC analysis

The results of the EAC base case analysis are presented in Table 4.8. For inputs used in the base case analysis please refer to Table 4.7.

Table 4.8: Base-case analysis results

	Mepilex Border	Standard care	Incremental cost per patient
Dressings	£58	£0	£58
Staffing costs	£12	£0	£12
Pressure ulcer treatment costs	£92	£181	-£89
Total	**£162**	**£181**	**-£19**

Figure 4.2: Cost breakdown chart

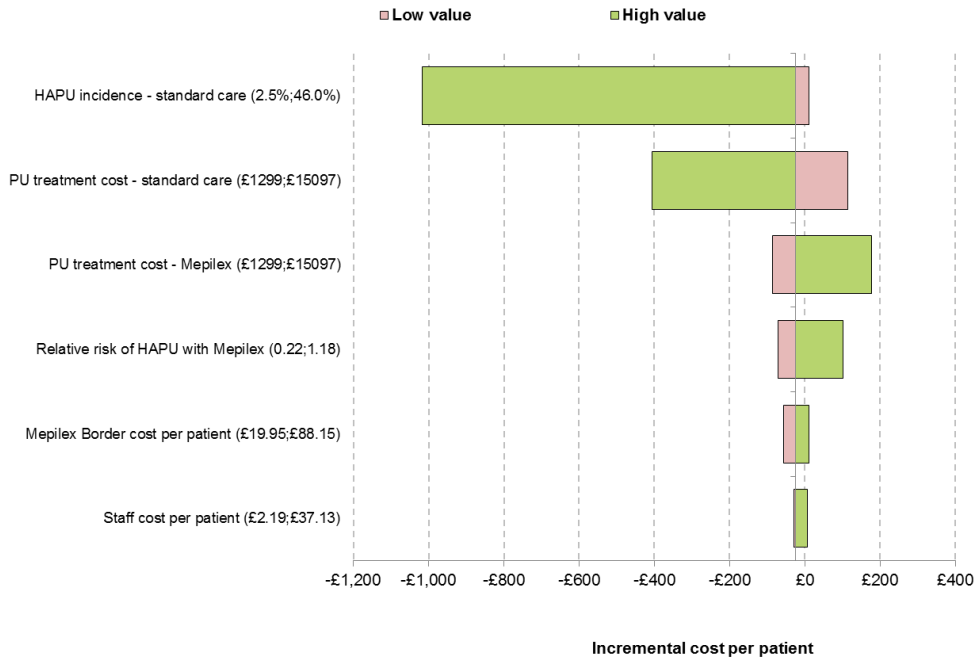


Sensitivity analysis results

The EAC identified a plausible range for each input parameter and varied the input parameter within this range. The parameters and ranges of values used for the EAC's sensitivity analysis are given in Appendix K.

Univariate sensitivity analyses were conducted and the results of this are presented in Figure 4.3. The key drivers of the analysis as shown in the tornado diagram are pressure ulcer incidence with standard care, pressure ulcer treatment cost and relative risk of pressure ulcer with Mepilex Border dressings. Notably, reducing the number of Mepilex Border Heel and Sacrum Dressings to 2 and 4 respectively (in line with a 4.8 day rather than 9 day ICU stay) increases the estimated cost savings to £46 per patient.

Figure 4.3: Tornado diagram based on EAC sensitivity analysis



The EAC also conducted 2-way sensitivity analyses to explore the interaction between pressure ulcer treatment cost in the standard care and Mepilex arms, and between pressure ulcer incidence in the standard care arm and the relative risk of pressure ulcer with Mepilex. The results of these are presented in Figures 4.4 and 4.5 below. Pressure ulcer treatment costs were varied between the cost of treatment for the stage 1 pressure ulcer and the cost of treatment for a stage 4 pressure ulcer (Dealey et al. 2012). This range was chosen in order to fully test the assumption of uniform improvement with Mepilex Border dressings. However, it is unlikely that the difference between the pressure ulcer treatment costs would ever vary this widely in practice. Pressure ulcer incidence in the standard care arm was varied between the lowest incidence rate (Walker et al. 2017) identified in the clinical review and the highest (Park 2014).

Figure 4.4: Two way sensitivity analyses - pressure ulcer treatment costs

		PU treatment cost - Mepilex Border									
	-£19	£1,299	£2,832	£4,365	£5,898	£7,431	£8,965	£10,498	£12,031	£13,564	£15,097
PU treatment cost - standard care	£1,299	£46	£75	£105	£113	£134	£164	£193	£222	£252	£281
	£2,832	-£12	£18	£47	£56	£76	£106	£135	£165	£194	£223
	£4,365	-£69	-£40	-£11	-£2	£19	£48	£78	£107	£136	£166
	£5,898	-£127	-£98	-£68	-£59	-£39	-£9	£20	£49	£79	£108
	£7,431	-£185	-£155	-£126	-£117	-£96	-£67	-£38	-£8	£21	£51
	£8,965	-£242	-£213	-£184	-£175	-£154	-£125	-£95	-£66	-£37	-£7
	£10,498	-£300	-£271	-£241	-£232	-£212	-£182	-£153	-£124	-£94	-£65
	£12,031	-£358	-£328	-£299	-£290	-£269	-£240	-£211	-£181	-£152	-£122
	£13,564	-£415	-£386	-£356	-£348	-£327	-£298	-£268	-£239	-£209	-£180
	£15,097	-£473	-£443	-£414	-£405	-£385	-£355	-£326	-£296	-£267	-£238

Figure 4.5: Two way sensitivity analysis – pressure ulcer incidence

		Relative risk of HAPU with Mepilex Border									
	-£19	0.00	0.12	0.24	0.36	0.48	0.60	0.72	0.84	0.96	1.08
HAPU incidence standard care	3%	-£51	-£36	-£22	-£7	£7	£22	£36	£51	£65	£79
	7%	-£284	-£241	-£199	-£157	-£114	-£72	-£29	£13	£56	£98
	12%	-£517	-£447	-£376	-£306	-£235	-£165	-£94	-£24	£46	£117
	17%	-£750	-£652	-£553	-£455	-£357	-£258	-£160	-£61	£37	£135
	22%	-£983	-£857	-£730	-£604	-£478	-£351	-£225	-£99	£28	£154
	27%	-£1,216	-£1,062	-£908	-£753	-£599	-£445	-£290	-£136	£18	£173
	32%	-£1,449	-£1,267	-£1,085	-£902	-£720	-£538	-£356	-£173	£9	£191
	36%	-£1,683	-£1,472	-£1,262	-£1,052	-£841	-£631	-£421	-£211	£0	£210
	41%	-£1,916	-£1,677	-£1,439	-£1,201	-£963	-£724	-£486	-£248	-£10	£229
	46%	-£2,149	-£1,883	-£1,616	-£1,350	-£1,084	-£818	-£551	-£285	-£19	£247

Threshold analysis was conducted around all key parameters, and the results of this are shown in Table 4.8.

Table 4.8: Threshold values

Parameter	EAC base case value	Threshold value*	Plausibility
Baseline risk of pressure ulcer standard care	3.8%	3.0%	This is within the ranges tested in sensitivity analysis and is above the lowest rate identified in the clinical review so the EAC deems this would be plausible, however, the EAC notes the baseline risk of pressure ulcer is likely to vary widely depending on the hospital, the setting within the hospital and the risk of the patient.
Relative risk of pressure ulcer with Mepilex Border dressings	0.51	0.61	This is within the confidence interval calculated by the EAC and is, therefore, plausible.
Number of Mepilex Border Sacrum dressings per patient	4	7	Assuming a dressing change every 2 to 3 days would mean a hospital stay of between 14 and 21 days. Data suggests the average length of stay in an ICU in the UK is 4.8 days (Intensive care national audit & research centre (icnarc) 2018). The baseline incidence of pressure ulcer with standard care in the model is based on NHS data for ICU so patients with an extended length of stay of 14 to 21 days may also have a higher baseline incidence of pressure ulcer as they are in hospital for longer so this may not be plausible in line with other inputs in the model.
Number of Mepilex Border Heel dressings per patient	6	8	Assuming the dressing is changed on both heels every 3 days, this would mean a hospital stay of 12 days. Patients with this length of stay may also have a higher baseline incidence of pressure ulcer as they are in hospital for longer so this may not be plausible in line with other model inputs.
Staff costs per patient	£12.33	£31.34	This is within the ranges tested by the EAC in sensitivity analysis. Higher staff costs could result from a higher band of nurse replacing the dressings, more dressings per patient or an increase in the length of time taken to change a dressing. For example the high value used in sensitivity analysis was based on an increase of 1 sacrum dressing and 4 heel dressings per patient, a higher nurse cost based on an average of bands 5 to 8a, and 3 minutes being required per dressing change.
Pressure ulcer treatment cost	£4,823	£3,791	The cost of a stage 1 pressure ulcer is reported to be £1,299 (Dealey et al. 2012) so this value is plausible. However, this threshold value assumes pressure ulcer treatment costs are equal between both arms. These values may differ in each arm depending on whether Mepilex reduces the incidence of different

Parameter	EAC base case value	Threshold value*	Plausibility
			stages of pressure ulcers non-uniformly (See 2-way sensitivity analysis in Figure 4.4)
*A Threshold value is the value that generates a cost neutral result.			

Probabilistic sensitivity analysis

The EAC ran probabilistic sensitivity analysis varying all input parameters in the model to account for combined uncertainty in parameters. In particular there appears to be a lot of uncertainty around key input parameters including the baseline rate of pressure ulcer incidence with standard care and the relative risk of pressure ulcer with Mepilex Border dressings. Distributions used are shown in Appendix K.

Two PSA scenarios were run, with 2,000 iterations each. Firstly, assuming the costs of pressure ulcer treatments were equal between both arms i.e. Mepilex Border dressings are assumed to reduce the incidence of pressure ulcer uniformly across all stages of pressure ulcer. Second, assuming pressure ulcer treatment costs can vary between both arms i.e. the proportions of each grade of pressure ulcer were varied independently in each arm to incorporate the uncertainty around Mepilex Border dressings reducing the incidence of pressure ulcer more for lower *or* higher stages of pressure ulcer. The results of these analyses are shown in Figures 4.6 and 4.7, with red bars showing iterations where the results of the model were cost incurring and green bars showing iterations where the results were cost saving.

Figure 4.6: Probabilistic sensitivity analysis results – equal pressure ulcer treatment costs

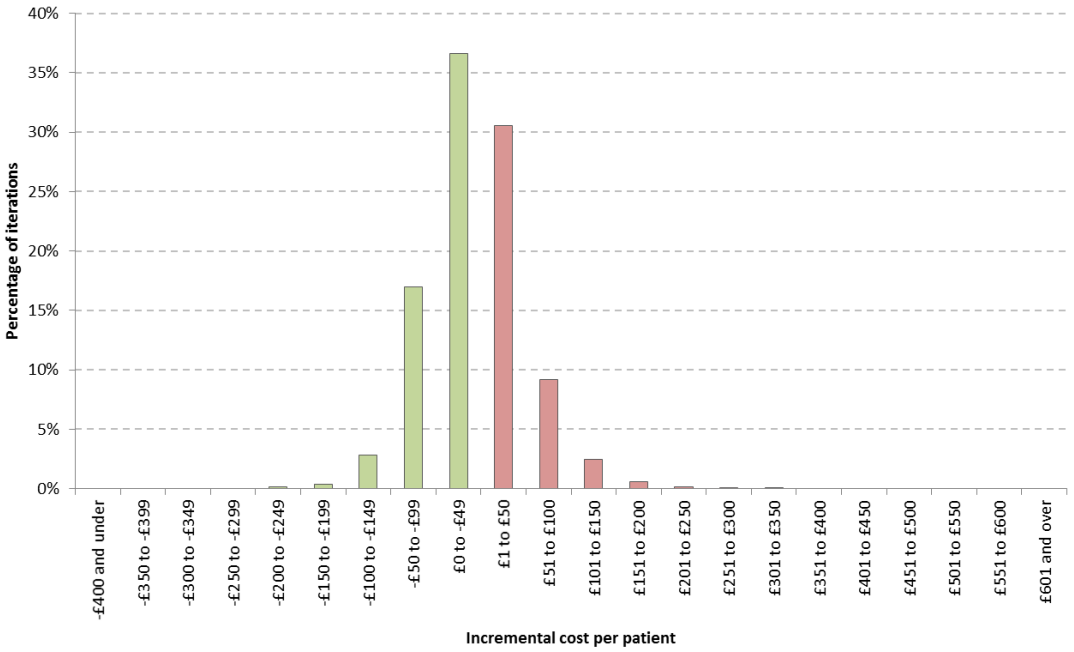
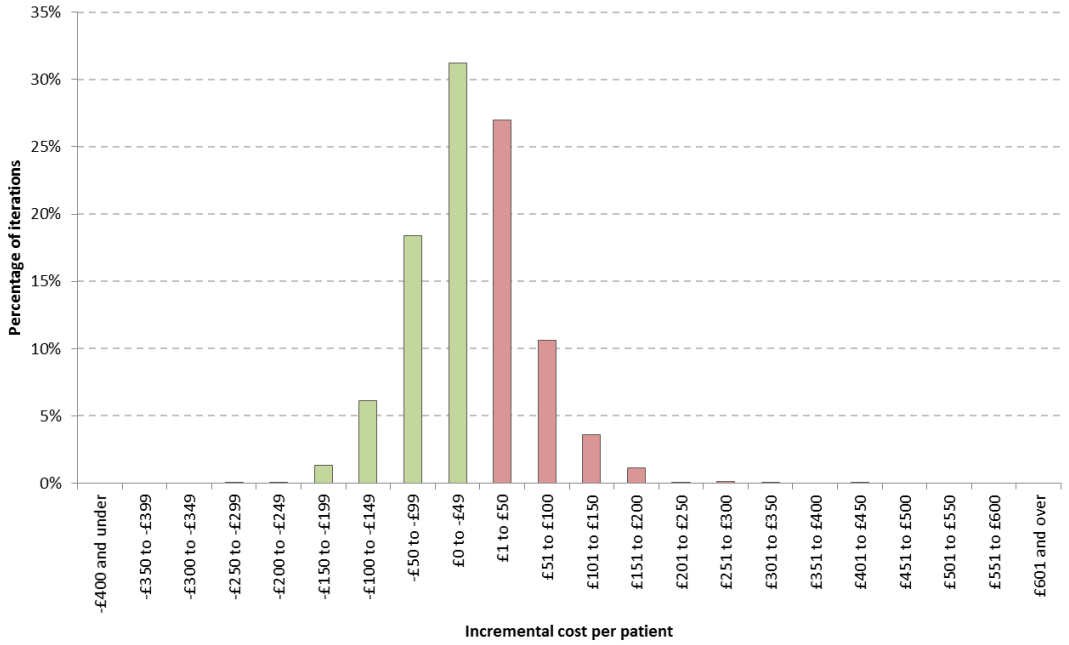


Figure 4.7: Probabilistic sensitivity analysis results – pressure ulcer treatment costs varied independently



Running the PSA for the first scenario (equal pressure ulcer treatment costs) resulted in an estimated probabilistic cost saving of £6.55, with an estimated probability of being cost saving of 57%. The estimated probabilistic cost saving is lower than the deterministic cost saving because the average probabilistic relative risk of pressure ulcer is 0.56 compared with 0.51 in the base case. This discrepancy reduces the treatment effectiveness of Mepilex Border dressings and therefore the estimated cost savings.

Running the PSA with pressure ulcer treatment costs varying independently increased the probabilistic cost saving estimate to £8.94, with the same estimated probability of being cost saving of 57%. This indicates that varying this parameter independently does not have a significant impact on the results.

Scenario analysis

The EAC ran a scenario analysis using the meta-analysed data from 4 RCTs reported in Section 3.8. This analysis is subject to the assumption that the data from Santamaria 2015a equates to 1 pressure ulcer per patient. The results of this analysis are presented in Table 4.9. Under this scenario the results of the model are still sensitive to plausible changes in model input parameters.

Table 4.9: Results of sacrum pressure ulcer scenario analysis

	Mepilex	Standard care	Incremental cost per patient
Dressings	£58	£0	£58
Staffing costs	£12	£0	£12
Pressure ulcer treatment costs	£76	£181	-£105
Total	**£146**	**£181**	**-£35**
Probability of cost saving			**73%**

Subgroup analysis

The EAC ran a subgroup analysis to assess the impact of Mepilex Border dressings on sacral pressure ulcers only. The majority of the clinical evidence including the 3 key RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Walker et al. 2017) that contributed to the relative risk estimate from the meta-analysis only assess the effect of Mepilex Border dressings on sacral pressure ulcers. Therefore, the cost of heel dressings and associated staff time were excluded from the analysis, and the baseline incidence of pressure ulcer in the standard care arm was reduced to 2.15% to account for sacral pressure ulcers only

(36.5% of pressure ulcers are sacrum (Clark et al. 2017), so 5.9% deflated by this, see Section 4.2.5 for more details). All other variables were kept consistent with the base case analysis. The results of this analysis are presented in Table 4.10.

Table 4.10: Results of sacrum pressure ulcer scenario analysis

	Mepilex	Standard care	Incremental cost per patient
Dressings	£19	£0	£19
Staffing costs	£5	£0	£5
Pressure ulcer treatment costs	£53	£104	-£51
Total	**£76**	**£181**	**-£27**
Probability of cost saving			**81%**

A subgroup analysis was also run for Mepilex Border Heel dressings only based on the only comparative evidence assessing these dressings (Santamaria et al. 2015b). The relative risk of pressure ulcer incidence with Mepilex Border dressings was changed to 0 to reflect the trial incidence, and the baseline incidence of pressure ulcers with standard care was reduced to 1.6% to account for heel pressure ulcers only (27.3% of pressure ulcers are heel (Clark et al. 2017), so 5.9% multiplied by this, see Section 4.2.5 for more details). The cost of sacrum dressings and associated nurse time were also excluded from the analysis, but all other variables were kept consistent with the base case analysis. This exploratory scenario was found to be cost saving with an estimated saving of £31 per patient. PSA was not run for this scenario as there was no confidence interval reported with which to vary the relative risk. However, given that these data are available from 1 trial only, there is likely much uncertainty in the relative risk of pressure ulcers.

To explore the impact of using Mepilex Border dressings (general variant rather than specific to heel or sacrum) used on the sacrum or heel a scenario was run. This scenario assumed the clinical efficacy of Mepilex Border dressings can be considered to be equivalent to that reported in the clinical evidence for Mepilex Border Heel and Mepilex Border Sacrum dressings. No RCT evidence was identified for Mepilex Border dressings applied to the heel or sacrum. It was also assumed no additional nursing time would be required to apply these dressings. Therefore, only the costs of the dressings were changed, with all other parameters being kept consistent with the base case.

Prices were obtained for all Mepilex Border dressings (not specific to heel or sacrum) and any dressings smaller than that available for the heel and sacrum variants were excluded on the basis that these would be too small to be used on the heel or sacrum. Scenarios were then run for the lowest (£2.90) and

highest (£5.12) unit cost identified. The results of this scenario are presented in Tables 4.11 and 4.12.

Table 4.11: Mepilex Border dressing scenario results – low cost of dressing (£2.90)

	Mepilex Border (genera variant)	Standard care	Incremental cost per patient
Dressings	£29	£0	£29
Staffing costs	£12	£0	£12
Pressure ulcer treatment costs	£92	£181	-£89
Total	**£134**	**£181**	**-£48**
Probability of cost saving			**77%**

Table 4.12: Mepilex Border dressing scenario results – high cost of dressing (£5.12)

	Mepilex	Standard care	Incremental cost per patient
Dressings	£51	£0	£51
Staffing costs	£12	£0	£12
Pressure ulcer treatment costs	£92	£181	-£89
Total	**£156**	**£181**	**-£25**
Probability of cost saving			**63%**

Model validation

The EAC's model was internally validated. All input parameters and calculations were checked and verified by a second health economist. The EAC was unable to find external sources set within the NHS against which to validate its results. Therefore, clinical consequences were assessed against the clinical studies to confirm that the model gave reasonable estimates.

4.5 EAC Interpretation of economic evidence

The results of the EAC's analysis comparing Mepilex Border Sacrum and Heel dressings as an adjunct to standard care with standard care alone is reported in Table 4.13. This table shows the impact of each individual change made by the EAC on the results of the company's model. Changes made by the EAC both increased and reduced cost savings compared with the company model, with the most significant change resulting from the alteration of the baseline pressure ulcer incidence with standard care and the pressure ulcer incidence with Mepilex Border dressing.

The magnitude of cost savings reduced significantly in the EAC analysis. However, the direction of the results did not change.

Table 4.13: Impact on the cost difference between the technology and comparator of additional clinical and economic analyses undertaken by the External Assessment Centre

EAC change	EAC result: incremental cost per patient*	Change from company's base case**	Proportion of company incremental cost***	Impact of action (compared with company's base case incremental cost of -£177 per patient)
Company's base case result	**-£177**	NA		
Incidence of pressure ulcer (standard care) changed from 13.1% to 3.8%, and risk of pressure ulcer with Mepilex Border dressings changed from 3.1% to 1.9% through use of relative risk (0.51)	£66	+£243	-37%	Resulted in cost incurring result due to large reduction in baseline risk with standard care. The direction of results changed compared to company's base case.
Number of Mepilex Border Sacrum dressings increased from 2 to 4 dressings per patient (associated staff time increased by 4 minutes)	-£144	+£33	81%	Minor impact on results, cost saving was reduced but did not change the direction of results. Company's base case cost saving reduced by 19%.
Number of Mepilex Border Heel dressings increased from 4 to 6 dressings per patient (associated staff time increased by 4 minutes)	-£139	+£39	79%	Minor impact on results, cost saving was reduced but did not change the direction of results. Company's base case cost saving reduced by 21%.
Cost of Mepilex Border Sacrum dressing changed from £4.44 to £4.63. Cost of Mepilex Border Heel dressing changed from £7.21 to £6.50.	-£180	-£3	101%	Negligible impact on results. Cost saving increased by 2%.
Total staff time cost per patient reduced from £72.80 to £12.33 to correct for incorrectly calculating yearly costs. (Total minutes required for dressing changes also increased from 12 minutes to 20 minutes due to increase in dressing changes and cost per minute of nurse time also updated to current price year using PSSRU 2017)	-£238	-£60	134%	Increased cost savings by 34% from company base case, largely due to the correction of the error in application of staff costs
Cost of pressure ulcer treatment in Mepilex arm changed from £3,858 to £4,823. Cost of pressure ulcer treatment in standard care arm changed from £3,111 to £4,823.	-£372	-£194	210%	Large increase in cost savings of 110% from company base case due to more significant increase in pressure ulcer treatment cost in standard care arm.

EAC change	EAC result: incremental cost per patient*	Change from company's base case**	Proportion of company incremental cost***	Impact of action (compared with company's base case incremental cost of -£177 per patient)
All changes made simultaneously (EAC base case)	-£19	+£158	11%	Significant reduction of 89% in cost savings compared to company base case, but direction of results remains unchanged.

* Negative results indicate cost savings.
** Negative results indicate an *increase* in cost savings from the company's base case.
*** This is calculated as "EAC result: incremental cost per patient" for each row, divided by the Company's base case result.

5 Conclusions

5.1 Conclusions on the clinical evidence

The EAC conducted a full critique of the company's clinical review; 13 studies reported across 23 publications were included by the EAC.

The clinical evidence comprises:

- Four RCTs (Aloweni et al. 2017, Kalowes et al. 2016, Santamaria et al. 2015a, Walker et al. 2017).
- Nine non-randomised comparative observational studies (Brindle and Wegelin 2012, Chaiken 2012, Cubit et al. 2013, Haisley et al. 2015, Jin 2018, Park 2014, Richard-Denis et al. 2017a, Santamaria et al. 2015b, Yoshimura et al. 2016).

All 4 of the RCTs and the majority of non-randomised comparative studies recruited adult patients at high-risk of pressure ulcers in ICUs, medical/surgical wards and emergency departments. Whilst the evidence is generally well matched with the population defined in the scope, there is limited evidence concerning patients at lower risk of developing pressure ulcers.

Mepilex Border Sacrum dressings plus standard care was the main intervention in all 4 of the RCTs and the majority of non-randomised comparative studies. One study assessed Mepilex Border Heel dressings and 1 assessed Mepilex Border dressings (applied to the sacrum). The EAC considers the volume and quality of comparative evidence for Mepilex Border Sacrum dressings to be sufficient. Comparative evidence associated with the Mepilex Border Heel dressing and Mepilex Border (applied to the heel or sacrum) dressings is limited. The EAC notes, however, that in both the study assessing Mepilex Border Heel dressings and the study assessing Mepilex Border dressings, the results showed a statistically significant difference in favour of the intervention ($p = <0.001$).

Standard NHS clinical practice is the comparator of interest to the decision problem, and may involve a combination of different components of care for pressure ulcer prevention. However, the way in which components of care are delivered may vary between patient setting and location. This point was reflected in the evidence identified and also by clinical experts in response to questions from the EAC (Correspondence log). Across the RCTs, specific components of standard care were aligned with the scope, including pressure redistribution, regular positioning and skin care, skin assessment and risk assessment by Braden score. The majority of non-randomised comparative studies also reported a mixture of components aligning with the scope. Overall,

the EAC considered the evidence to be well matched with the decision problem in terms of the eligible comparator.

Studies reported on few outcomes of interest to the decision problem, with pressure ulcer incidence the most commonly reported. The EAC pooled the results of 3 RCTs (all comparing Mepilex Border Sacrum dressings plus standard care with standard care alone) in relation to the number of patients developing pressure ulcers. The analysis showed that whilst the point estimate is in favour of the intervention, the difference is not significant (RR 0.51 [95% CI 0.22 to 1.18] p = 0.12). Where the data from all 4 RCTs were included, under the assumption of equivalence in terms of number of pressure ulcers and patients with pressure ulcers, the difference became significant (RR: 0.42 [95% CI 0.20 to 0.86], p=0.02).

Limited evidence were available for other outcomes. Where results relating to the stage of pressure ulcers were reported, higher stage pressure ulcers typically developed in patients not receiving the intervention. In terms of patient comfort and satisfaction, results showed that in the majority of self-assessments, patients reported the intervention as comfortable. In terms of usability a study stated there were some difficulties associated with reapplying the dressing and keeping it in place when patients were restless.

Key uncertainties with the evidence base include limited data for Mepilex Heel and Mepilex Border (applied to the heel or sacrum) dressings, patients 'at risk' but not 'at high risk' of pressure ulcers and paediatric patients. Further, many of the outcomes of interest to the decision problem are not addressed by the evidence (see Table 2.3).

5.2 Conclusions on the economic evidence

Neither the company nor the EAC identified any UK published economic studies, but those set in Australia estimated that Mepilex Border dressings are cost saving.

The *de novo* model submitted by the company was fully executable. No structural changes were made to the company model. However, all input parameters were updated by the EAC to improve its usefulness and generalisability to the UK NHS (described in Section 4.2.5 and 4.2.6).

The company model reported mean cost savings per patient of £177. Following the EAC's revisions, the estimated cost saving was reduced to £19 per patient, with a probability of being cost saving estimated at 57%. Although EAC revisions did not change the direction of the results, sensitivity analyses showed that these results were highly sensitive to changes in all input parameters. Furthermore, values required to generate cost increasing results appeared to

be plausible for the majority, if not all, input parameters. This indicates uncertainty around the results produced.

The EAC notes that the relative risk of pressure ulcer incidence calculated in the meta-analysis and used in the EAC model was based only on the effectiveness of Mepilex Border Sacrum dressings due to a lack of randomised evidence for Mepilex Border Heel dressings. Therefore, within the EAC's base case the treatment effect for Mepilex Border Heel dressings is assumed to be equal to Mepilex Border Sacrum dressings (judged appropriate based on the 1 available non-randomised comparative study (Santamaria et al. 2015b)). Given the limited evidence on Mepilex Border Heel dressings the intervention in the scope of the decision problem could not be fully addressed. In response to this, the EAC ran a scenario analysis assessing Mepilex Border Sacrum dressings only, which increased the cost savings to £27 per patient and the probability of being cost saving to 81%.

The patients included in the meta-analysis (reported in Section 3.8) were those at *high* risk of pressure ulcers. There was limited evidence in patients at risk, rather than at high risk of pressure ulcers so, again, it was not possible to fully address the scope of the decision problem with regards to the population. The use of evidence in high risk patients to derive a treatment effect may limit the generalisability of this treatment effect to lower risk patients as the scope to benefit from Mepilex Border dressings could be increased in the high risk group.

A further limitation of the analysis is that it was not possible to ascertain how the use of Mepilex Border dressings impacted on the stage of pressure ulcer, due to the low incidence of pressure ulcers in the trials (Table 3.8). The direction of bias in the model's results is unknown and depends on whether higher stage pressure ulcers were reduced more or less than lower stage pressure ulcers, and whether, if a pressure ulcer was developed, the stage was reduced by the use of the Mepilex Border dressings. The model estimates cost savings providing that pressure ulcer treatment costs in the Mepilex Border dressings arm are no more than around £1,000 more than in the standard care arm when costs in the standard care arm are set to the base case value of £4,823 (see Figure 4.4).

Further uncertainty exists around the baseline rate of pressure ulcer and this is likely to vary widely between different hospitals, patients and risk groups. Where the baseline risk of pressure ulcer in standard care is over 3%, Mepilex Border dressings are estimated to be cost saving with an estimated probability of cost saving of 44%. Where the baseline risk of pressure ulcers is lower than 3% there is not enough scope to benefit from Mepilex Border dressings to generate cost savings. However, it should also be noted that the absolute reduction of 1.8% of pressure ulcers (calculated baseline pressure ulcer

incidence of 3.76% minus Mepilex Border incidence of 1.92%) will also have positive implications for patients' quality of life which is not captured within the analysis.

6 Summary of the combined clinical and economic sections

There is a reasonably large body of comparative evidence for Mepilex Border Sacrum dressings (plus standard care) compared with standard care alone in relation to the incidence of developing pressure ulcers. Whilst the trend in evidence favours Mepilex Border Sacrum dressings, the majority of studies do not report a statistically significant difference between the intervention and comparator. Further, none of the studies have been conducted in the UK. The evidence for Mepilex Border Heel dressings is limited to 1 non-randomised comparative study. The EAC's cost analysis estimates that Mepilex Border Sacrum and Heel dressings generate cost savings. However, there is uncertainty around this. Subgroup analyses indicate that there is less decision uncertainty around the use of Mepilex Border Sacrum dressings (estimated deterministic cost saving of £27 per patient and 81% likelihood of being cost saving). In patient populations or settings with a higher pressure ulcer incidence higher cost savings may be realised (subject to the uncertainty in the treatment effect). Wider benefits of reducing the pressure ulcer incidence include the impact on patient's quality of life and freeing up resources within the NHS.

7 Implications for research

There is limited comparative evidence for Mepilex Border Heel and Mepilex Border (applied to the sacrum) dressings. There are also gaps in the evidence base concerning many of the outcomes defined in the scope, including level of patient satisfaction, additional length of hospital stay as a result of pressure ulcers, patient compliance, ease of use and device related adverse events.

A large scale, multicentre, RCT conducted in a UK setting is an option to help to overcome the limitations and remaining uncertainties with the evidence. Such a trial should ideally adhere to the following design:

- Assessing a broad population consisting of patients 'at risk' and 'at high risk' of developing pressure ulcers in various clinical settings.
- Comparing Mepilex Border Sacrum, Mepilex Border Heel and Mepilex Border dressings (applied to the heel or sacrum) to standard NHS clinical practice.

- Sufficiently powered with a predefined primary outcome (i.e. incidence of developing pressure ulcers) based on a clear estimate of clinically significant effect.

- Outcomes including all those defined in the scope of the decision problem.

The EAC accepts that such a study would be a very expensive undertaking. A large scale ongoing RCT (NCT03442777), set in Belgium, which was identified by the EAC, may help to address some of the concerns once completed.

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Appendices

Appendix A: Clinical evidence: critique of company's search methods, details of re-run company's searches, details of EAC *de novo* search methods and PRISMA diagram

Appendix B: Exclusion reasons by the EAC based on reassessment of the included studies using the company's selection criteria

Appendix C: List of excluded studies by the EAC

Appendix D: Detailed critical appraisal of randomised controlled trials

Appendix E: Detailed critical appraisal of comparative observational studies (CASP)

Appendix F: Issues identified by the EAC with the company's report of results

Appendix G: List of single arm studies not reporting device-related adverse event data

Appendix H: Economic evidence: critique of company's search methods, details of re-run company's NHS EED search and PRISMA diagram

Appendix I: Drummond checklist on company model and submission

Appendix J: EAC search strategy for baseline pressure ulcer incidence and pressure ulcer treatment costs

Appendix K: EAC's sensitivity analysis

Appendix A: Clinical evidence: critique of company's search methods, details of re-run company's searches, details of EAC *de novo* search methods and PRISMA diagram

Critique of the company's search methods to identify clinical evidence

The Peer Review of Electronic Search Strategies (PRESS) Checklist was used to inform the critique of the company's search strategies (McGowan et al. 2016). The PRESS checklist is an evidence-based tool used to critically appraise literature search strategies. The PRESS project was funded by the Canadian Agency for Drugs and Technologies in Health (CADTH) and this approach to peer reviewing search strategies is supported by the Cochrane Collaboration's Information Retrieval Methods Group (Sampson et al. 2008).

Search reporting

Details of the company's search methods are reported in Sections 7.1 and 10.9 of the submission.

The company clearly stated which bibliographic databases were used for the searches for published evidence. The interface used to search the databases was also clearly reported, as was the search date and date span of the search. The search strategies for bibliographic databases were reported in enough detail to enable reproduction, although the duplication of some search lines (S3 and S6; S8 and S5) and the resulting redundancy undermined clarity of reporting.

In submission Section 7.1.2 the company reported 2 activities for the search for unpublished evidence. The company conducted a hand-search of internal company documentation which included any evidence generated by Mölnlycke Health Care in any country, including confidential and unpublished evidence. The company also searched the Mölnlycke database of all known published or unpublished papers assessing Mepilex Border dressings. Only the second of these activities was reported in the Appendix. No further details were given regarding the internal company documentation or the Mölnlycke database (for example, how the content for these sources is populated and how they were searched). Further details would have enabled a fuller assessment of the company's search for unpublished evidence. No result numbers for the unpublished evidence search were reported in the submission Appendix. The number given in the PRISMA diagram (Figure A2, Submission) for 'Additional records identified through other sources' may relate to this search, but this was unclear.

Currency of searches

The MEDLINE and Embase searches were conducted on January 5th 2018. This was less than 3 months before submission. Although inevitably there is the possibility that relevant studies may have been published or added to the databases in the period between search date and submission completion, the company's searches, therefore, had reasonably good currency at the time of submission.

Search sources

The NICE submission template indicates that 4 sources are required as a minimum for searches for clinical evidence: MEDLINE, MEDLINE-IN-Process, Embase and the Cochrane Library. The company reported a search of MEDLINE and Embase. In-Process results are included in a search of MEDLINE using ProQuest Dialog, so the search of MEDLINE did include In-Process results. The company did not report a search of the Cochrane Library. The Cochrane Library (particularly the constituent databases Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects, Health Technology Assessment Database and Cochrane Database of Systematic Reviews) is commonly regarded as a key search resource for reviews of clinical effectiveness. Inclusion of the Cochrane Library as a source in the company's searches would therefore have enhanced search methodology. Given the topic, inclusion of key databases in the field of nursing (for example CINAHL and the British Nursing Index) would also have enhanced search methodology.

The NICE MTEP methods guide specifies that search sources should include conference proceedings. The company searched Embase, which includes abstracts from some conferences. The extent of any further searching for conference abstracts is not clear, although the company did cite conference abstracts in the submission. The company conducted a hand-search of 2 internal sources which included 'unpublished' evidence (internal company documentation and the Mölnlycke database of all known published or unpublished papers assessing Mepilex Border dressings), but the extent to which the content of these 2 sources captured conference abstracts is not known.

The MTEP methods guide indicates that search sources should include registers or databases of ongoing clinical trials. The company did not report a search of any trial registers. Inclusion of trial registers as a source in the company's searches would have enhanced search methodology.

Bibliographic databases: search strategy structure, search terms, syntax and restrictions

Both the MEDLINE and Embase searches were run in ProQuest Dialog. It was not possible for the EAC to be certain how some aspects of the reported search strategies would have been interpreted by the ProQuest Dialog interface, as the interface preference settings at the time of search were not reported. Preference settings in ProQuest Dialog determine, for example, whether the search retrieves records including plurals, spelling variants and variant forms, if these are not explicitly included in the search syntax. In the absence of this information, the EAC critiqued the company's search strategy on the basis of the terms as explicitly reported in the submission.

The company's bibliographic search strategy combined the following search concepts: pressure ulcers AND (Mepilex or foam dressing) AND prevention. The concepts were combined appropriately using Boolean. Including the 'prevention' concept was a relatively focused approach, given the systematic literature search context. Not including this concept might have enhanced search methodology, particularly given the very low numbers of records returned.

The company's bibliographic database search strategies did not include distinct subject heading searches and free text searches across specific fields (the approach commonly used in systematic literature searches). Instead, the terms were searched across all fields. Taking this approach can increase the risk of missing key index terms. For example, the company's Embase strategy does not include, or search on, the main subject heading used in Embase for pressure ulcers i.e. *Decubitus*. Including all appropriate index terms would have enhanced search methodology.

The search strategies included appropriate free-text terms for each search concept, though the range of variant terms included for some concepts was limited given the systematic literature search context. The limited range of variant terms potentially increased the risk of missing relevant studies. A good range of free-text terms was included for the pressure ulcer concept. Search methodology would have been enhanced by including additional free-text terms to retrieve potential variants for dressings, (for example, '*bandages*') and by including variants for foam, (for example, '*silicone*' and '*polyurethane*'). Similarly, terms for the prevention concept would have been enhanced by inclusion of variants such as '*prophylactic*'. Truncation was explicitly used for some terms (for example, *ulcer** and *prevent**). However, truncation was not used on other terms where this would have been appropriate (for example, truncation of *dressing** to include dressing*s*, truncation of *injur** to include injur*ies,* or truncation of *mepilex** to include mepilex*TM*). Appropriate truncation

would have enhanced the company's search methodology (though as noted above, the ProQuest Dialog preference settings at time of search may have meant that plurals and variant forms *were* included when the search interface processed the search, even though not explicitly included by the reported search terms or syntax).

No spelling errors were identified and the use of Boolean operators to combine free text was appropriate. The use of Boolean '*AND*' rather than proximity operators to combine free text terms increased search sensitivity, though at the expense of precision.

The searches were not restricted by language or study design. This was an appropriately sensitive approach – the NICE MTEP methods Guide indicates that searches should typically include studies of any type, including non-UK studies. No date restrictions were applied to the search, although the selection criteria in the submission (Table B1) indicated that studies were only considered if published after the introduction of Mepilex dressings (2001). Given the selection criteria date limit, a date limit applied at search would have improved search precision.

Details of re-run company's searches

The EAC did not have access to the interface used by the company to search MEDLINE and Embase (ProQuest Dialog) for the purpose of downloading records. The EAC also did not have access to the internal resources used by the company to search for unpublished evidence. The EAC was therefore unable to replicate the company's searches. Although replicating the searches was not possible, the EAC did translate the company's MEDLINE and Embase ProQuest Dialog search strategies for the Ovid interface, and ran the searches in this platform. The EAC Ovid translation reflected the ProQuest Dialog syntax as explicitly reported. As previously noted, ProQuest Dialog preference settings at the time of the company's search (which are not reported) may have meant that the company's searches did retrieve records including plurals, spelling variants and variant forms which were not explicitly included in the search syntax.

The searches described below approximate a re-run of the company's searches within the limitations of the search resources available to the EAC. They should not be considered a replication of the company's search methods.

Re-run company's searches: information resources

The information resources searched for the re-run company's searches are shown in Table A1.

Table A1: Re-run company's searches: Databases and information sources searched

Resource	Interface / URL
Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)	OvidSP
Embase	OvidSP

Results of the searches were downloaded and imported into EndNote reference management software. The records were deduplicated using several algorithms.

Re-run company's searches: literature search results

The re-run company's searches identified 170 records (Table A2). Following deduplication, 124 records were assessed for relevance.

Table A2: Re-run company's searches: Literature search results

Resource	Number of records identified
Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)	59
Embase	111
Total number of records retrieved	**170**
Total number of records after deduplication	**124**

Re-run company's searches: full search strategies

1: Source: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)

Interface / URL: OvidSP

Database coverage dates: 1946 to present

Search date: 18/04/18

Retrieved records: 59

Search strategy:

1 ((bed and sore*) or bedsore* or (pressure and (ulcer* or sore* or injury)) or (decubitus and (ulcer* or sore* or injury))).af. (67623)

2 (mepilex or (foam and dressing)).af. (614)

3 1 and 2 and prevent*.af. (59)

2: Source: Embase 1974 to 2018 April 17

Interface / URL: OvidSP

Database coverage dates: 1974 to 2018 April 17

Search date: 18/04/18

Retrieved records: 111

Search strategy:

1 ((bed and sore*) or bedsore* or (pressure and (ulcer* or sore* or injury)) or (decubitus and (ulcer* or sore* or injury))).af. (117433)

2 (mepilex or (foam and dressing)).af. (1672)

3 1 and 2 and prevent*.af. (111)

Details of EAC *de novo* searches

A *de novo* literature search was undertaken by the EAC. The search aimed to identify evidence on the Mepilex Border Heel dressing, Mepilex Border Sacrum dressing and Mepilex Border dressing in patients at risk or at high risk of pressure ulcers.

A strategy was developed for MEDLINE (Ovid interface). The strategy was devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the PubMed PubReminer tool (http://hgserver2.amc.nl/cgi-bin/miner/miner2.cgi). The approach taken to search strategy development aimed to balance sensitivity and precision, reflecting the project resources and timelines. The final strategy for MEDLINE is shown in Figure A1 below.

The main structure of the strategy consisted of 3 concepts:

1) Pressure ulcers. Search lines 1 – 6;

2) Dressings. Search lines 7 – 10.

3) Foam. Search lines 11 – 14.

The search concepts were combined as follows: pressure ulcers AND dressings AND foam.

The strategy also included additional lines which searched on terms considered highly relevant to the Mepilex dressings (e.g. redistribution of shear forces, dressing family name, company name and technology terms – search lines 16 - 25). These terms were combined with either both the pressure ulcer and dressing concepts (shear forces) or just the pressure ulcer concept (other terms). The strategy also included an additional stand-alone line on the specific dressing name of interest (search line 27).

The strategy excluded animal studies using a standard algorithm. Reflecting the date when Mepilex was introduced (as stated in the submission) the search was limited to studies published from 2001 to date. The search was not restricted by study design and no language limits were applied.

The final Ovid MEDLINE strategy was peer-reviewed by a second Information Specialist for errors in spelling, syntax and line combinations.

Figure A1: EAC search strategy for Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)

1	Pressure Ulcer/ (11241)
2	((pressure or deep tissue$) adj5 ulcer$).ti,ab,kf. (7311)
3	((pressure or deep tissue$) adj5 (sore$ or injur$ or lesion$)).ti,ab,kf. (8394)
4	decubit$.ti,ab,kf. (5140)
5	(bedsore$ or bed-sore$).ti,ab,kf. (651)
6	or/1-5 (22928)
7	exp Bandages/ (22641)
8	(bandage$ or dressing$).ti,ab,kf. (24510)
9	(layer or layers).ti,ab,kf. (331738)
10	or/7-9 (367991)
11	Polyurethanes/ (8640)
12	exp Silicones/ (25525)
13	(foam$ or silicon$ or polyurethan$ or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1).ti,ab,kf,rn,nm. (142170)
14	or/11-13 (145343)
15	6 and 10 and 14 (210)
16	6 and 10 and (Shear Strength/ or shear.ti,ab,kf.) (63)
17	Mepilex$2.af. (62)
18	Safetac$2.af. (16)
19	M?lnlycke$2.af. (145)
20	(5-layer$ or five-layer$ or 3-layer$ or three-layer$).ti,ab,kf. (6048)
21	(multi-layer$ or multilayer$).ti,ab,kf. (25630)
22	soft silicon$.ti,ab,kf. (260)
23	(silicon$ adj5 foam$).ti,ab,kf. (188)

24	((foam$ or silicon$ or polyurethan$) adj5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)).ti,ab,kf. (429)
25	or/17-24 (32215)
26	6 and 25 (102)
27	Mepilex$2 Border$2.af. (16)
28	15 or 16 or 26 or 27 (302)
29	exp animals/ not humans/ (4436130)
30	28 not 29 (288)
31	limit 30 to yr="2001 -Current" (236)
32	remove duplicates from 31 (236)

Key to Ovid symbols and commands

$	Unlimited right-hand truncation symbol
$N	Limited right-hand truncation - restricts the number of characters following the word to N
ti,ab,kf,rn,nm.	Searches are restricted to the Title, Abstract, Keyword Heading Word, Name of Substance Word, CAS Registry/EC Number/Name of Substance (RN) fields
af.	Searches are run across all fields
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other
/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
or/1-5	Combines sets 1 to 5 using OR
yr="2001 -Current")	Publication year 2001 to current

EAC *de novo* searches: information resources

The EAC conducted searches using each database or resource listed in Table A3, translating the final Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The information resources included a range of databases containing research published in the journal literature, conference abstracts and ongoing research. The searches were prospectively designed to identify both clinical and economic evidence and economics-specific databases were therefore included (NHS EED, EconLit and the Cost-Effectiveness Analysis (CEA) Registry). A hand search of 3 specific conferences for the last 3 years was also conducted (the European Pressure Ulcer Advisory Panel Annual Meeting, the Symposium on Advanced Wound Care Biannual (Spring / Fall) Event, and the Wound Ostomy and Continence Nurse Annual Conference). The 3 conferences were selected by the research team for hand-searching after viewing examples provided by the company of conferences at which data had been presented on Mepilex Border Heel or Mepilex Border Sacrum dressings. The research team then considered which of these were likely to be key conferences for Mepilex data and selected the 3 conferences above for hand-searching. The EAC also conducted focused searches of a selection of websites informed by the list of external organisations

identified on the NICE final scope document for the technology. The PubMed search was restricted to just records not fully indexed in MEDLINE.

Table A3: EAC de novo searches: databases and information sources searched

Resource	Interface / URL
Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)	OvidSP
Embase	OvidSP
Cochrane Central Register of Controlled Trials	Cochrane Library / Wiley
Database of Abstracts of Reviews of Effects	Cochrane Library / Wiley
Health Technology Assessment Database	https://www.crd.york.ac.uk/CRDWeb/
Cochrane Database of Systematic Reviews	Cochrane Library / Wiley
PubMed	http://www.ncbi.nlm.nih.gov/pubmed
Science Citation Index Expanded (SCI-EXPANDED)	Web of Science
Conference Proceedings Citation Index-Science (CPCI-S)	Web of Science
CINAHL Plus	EBSCOhost
British Nursing Index	ProQuest
Clinicaltrials.gov	https://clinicaltrials.gov/
WHO International Clinical Trials Registry Platform	http://apps.who.int/trialsearch/
ISRCTN registry	http://www.isrctn.com/
NHS Economic Evaluation Database (NHS EED)	Cochrane Library / Wiley
Econlit	OvidSP
Cost-Effectiveness Analysis (CEA) Registry	https://research.tufts-nemc.org/cear4/
European Pressure Ulcer Advisory Panel Annual Meeting	See full search strategy details
Symposium on Advanced Wound Care Biannual (Spring / Fall) Event	See full search strategy details
Wound Ostomy and Continence Nurse Annual Conference	See full search strategy details
Mölnlycke Health Care UK website pages on Mepilex Border, Mepilex Sacrum and Mepilex Heel	See full search strategy details
Association of Surgeons in Primary Care website	https://www.aspc-uk.net/
British Association of Dermatologists website	http://www.bad.org.uk/
British Dermatological Nursing Group website	https://bdng.org.uk/
British Geriatrics Society website	http://www.bgs.org.uk/
British Medical Ultrasound Society website	https://www.bmus.org/
British Orthopaedic Association website	http://www.boa.ac.uk/
British Orthopaedic Foot and Ankle Society website	https://www.bofas.org.uk/
British Skin Foundation website	http://www.britishskinfoundation.org.uk/
British Society for Dermatological Surgery website	https://www.bsds.org.uk/
Diabetes UK website	https://www.diabetes.org.uk/
European Wound Management Association website	http://ewma.org/
Intensive Care Society website	https://www.ics.ac.uk/

Resource	Interface / URL
Pressure Ulcer Research Service User Network website	http://medhealth.leeds.ac.uk/pursun
Paediatric Intensive Care Society website	http://picsociety.uk/
Primary Care Diabetes Society website	http://www.pcdsociety.org/
Primary Care Dermatology Society website	http://www.pcds.org.uk/
Royal College of Emergency Medicine website	http://www.rcem.ac.uk/
Royal College of General Practitioners website	http://www.rcgp.org.uk/
Royal College of Nursing website	https://www.rcn.org.uk/
Royal College of Physicians website	https://www.rcplondon.ac.uk/
Scottish Intensive Care Society website	https://www.scottishintensivecare.org.uk/
Society for Acute Medicine website	http://www.acutemedicine.org.uk/
Society of Chiropodists & Podiatrists website	https://www.scpod.org/
Society of Vascular Nurses website	http://www.svn.org.uk/
Society for Vascular Technology for Great Britain and Ireland website	https://www.svtgbi.org.uk/
Surgical Dressing Manufacturers Association website	https://www.dressings.org.uk/
Vascular Society website	https://www.vascularsociety.org.uk/
Tissue Viability Society website	https://tvs.org.uk/
UK Oncology Nursing Society website	http://www.ukons.org/
Welsh Wound Network website	http://www.welshwoundnetwork.org/en/
Wound Care Alliance UK website	https://www.wcauk.org/
Action Cerebral Palsy website	https://www.actioncp.org/
Action for Elder abuse website	https://www.elderabuse.org.uk/
Age Related Diseases and Health Trust website	http://www.agetrust.org/
Age UK website	https://www.ageuk.org.uk/
Bladder and Bowel UK website	http://www.bladderandboweluk.co.uk/
Brain and Spinal Injury Charity website	https://www.basiccharity.org.uk/
Brain and Spine Foundation website	https://www.brainandspine.org.uk/
British Obesity Surgery Patients Association website	http://www.bospa.org/
Cure Parkinsons Trust website	https://www.cureparkinsons.org.uk/
Diabetes Research & Wellness Foundation website	https://www.drwf.org.uk/
Diabetes UK website	https://www.diabetes.org.uk/
Foot in Diabetes UK website	http://www.footindiabetes.org/
Hoop UK website	http://hoopuk.org.uk/
ICU Steps website	http://www.icusteps.org/
Independent Age website	https://www.independentage.org/
Independent Diabetes Trust website	https://www.iddt.org/
Juvenile Diabetes Research Foundation website	https://jdrf.org.uk/
Leg Ulcer Charity website	http://legulcercharity.org/
Lindsay Leg Club Foundation website	https://www.legclub.org/
Multiple Sclerosis Society website	https://www.mssociety.org.uk/
Multiple Sclerosis Trust website	https://www.mstrust.org.uk/
Multiple Sclerosis-UK website	http://www.ms-uk.org/
National Obesity Forum website	http://www.nationalobesityforum.org.uk/
National Tremor Foundation website	http://www.tremor.org.uk/
Parkinson's UK website	https://www.parkinsons.org.uk/
Pressure Ulcers UK website	http://www.pressureulcers.uk/
Spinal Injuries Association website	https://www.spinal.co.uk/
The Circulation Foundation website	https://www.circulationfoundation.org.uk/
The Relatives and Residents Association website	http://www.relres.org/
Trauma Care website	https://www.traumacare.org.uk/

Resource	Interface / URL
Vascular Society for Great Britain and Ireland website	https://www.vascularsociety.org.uk/
Wound Care 4 Heroes website	http://www.woundcare4heroes.org.uk/

Three additional search sources were also sought, but were not accessible / not found at date of search:

- Euroscan (unable to access site using previously valid URL [https://www.euroscan.org/] on date of search – 'This site can't be reached' message returned). Unable to identify new URL at time of search. Dates tested: 28/09/03, 29/03/18 and 02/04/18).

- Southern Alliance of Tissue Viability Nurses website (no website found).

- Critical Care Patient Liaison Committee website (no website found).

In addition to the searches of the sources listed in Table A3, the EAC also checked reference lists in relevant studies and reviews which were identified and checked studies provided by the company.

Where possible, results of searches were downloaded in a tagged format and loaded into bibliographic software (EndNote). The results were deduplicated using several algorithms and the duplicate references held in a separate EndNote database for checking if required. Results from resources which did not allow export in a format compatible with EndNote were saved in Word or Excel documents as appropriate and manually de-duplicated.

EAC *de novo* searches: literature search results

The EAC searches identified 2073 records (Table A4). Following deduplication, 1,209 records remained.

Table A4: EAC *de novo* searches: literature search results

Resource	Number of records identified
Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R)	236
Embase	370
Cochrane Central Register of Controlled Trials	75
Database of Abstracts of Reviews of Effects	7
Health Technology Assessment Database	21
Cochrane Database of Systematic Reviews	17
PubMed	55
Science Citation Index Expanded (SCI-EXPANDED) / Conference Proceedings Citation Index- Science (CPCI-S)	218
CINAHL Plus	288

Resource	Number of records identified
British Nursing Index	126
Clinicaltrials.gov	227
WHO International Clinical Trials Registry Platform	207
ISRCTN registry	8
NHS Economic Evaluation Database	5
Econlit	0
Cost-Effectiveness Analysis (CEA) Registry	14
European Pressure Ulcer Advisory Panel Annual Meeting	22
Symposium on Advanced Wound Care Biannual (Spring / Fall) Event	34
Wound Ostomy and Continence Nurse Annual Conference	114
Mölnlycke Health Care UK website pages on Mepilex Border, Mepilex Sacrum and Mepilex Heel	16
Association of Surgeons in Primary Care website	0
British Association of Dermatologists website	0
British Dermatological Nursing Group website	0
British Geriatrics Society website	0
British Medical Ultrasound Society website	0
British Orthopaedic Association website	0
British Orthopaedic Foot and Ankle Society website	0
British Skin Foundation website	0
British Society for Dermatological Surgery website	0
Diabetes UK website	0
European Wound Management Association website	5
Intensive Care Society website	0
Pressure Ulcer Research Service User Network website	0
Paediatric Intensive Care Society website	0
Primary Care Diabetes Society website	0
Primary Care Dermatology Society website	0
Royal College of Emergency Medicine website	0
Royal College of General Practitioners website	0
Royal College of Nursing website	0
Royal College of Physicians website	0
Scottish Intensive Care Society website	0
Society for Acute Medicine website	0
Society of Chiropodists & Podiatrists website	0
Society of Vascular Nurses website	0
Society for Vascular Technology for Great Britain and Ireland website	0
Surgical Dressing Manufacturers Association website	0
Vascular Society website	0
Tissue Viability Society website	0
UK Oncology Nursing Society website	0
Welsh Wound Network website	0
Wound Care Alliance UK website	0
Action Cerebral Palsy website	0
Action for Elder abuse website	0
Age Related Diseases and Health Trust website	0
Age UK website	0
Bladder and Bowel UK website	0
Brain and Spinal Injury Charity website	0
Brain and Spine Foundation website	0
British Obesity Surgery Patients Association website	0
Cure Parkinsons Trust website	0
Diabetes Research & Wellness Foundation website	0

Resource	Number of records identified
Diabetes UK website	0
Foot in Diabetes UK website	0
Hoop UK website	0
ICU Steps website	0
Independent Age website	0
Independent Diabetes Trust website	0
Juvenile Diabetes Research Foundation website	0
Leg Ulcer Charity website	0
Lindsay Leg Club Foundation website	0
Multiple Sclerosis Society website	0
Multiple Sclerosis Trust website	0
Multiple Sclerosis-UK website	0
National Obesity Forum website	0
National Tremor Foundation website	0
Parkinson's UK website	0
Pressure Ulcers UK website	0
Spinal Injuries Association website	0
The Circulation Foundation website	0
The Relatives and Residents Association website	0
Trauma Care website	0
Vascular Society for Great Britain and Ireland website	0
Wound Care 4 Heroes website	0
Company contact	8
Reference list checking	0
Total number of records retrieved	2,073
Total number of records after deduplication	**1,209**

EAC *de novo* searches: full search strategies

1: Source: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) 1946 to Present

Interface / URL: OvidSP

Database coverage dates: 1946 to Present

Search date: 27/03/18

Retrieved records: 236

Search strategy:

1 Pressure Ulcer/ (11241)
2 ((pressure or deep tissue$) adj5 ulcer$).ti,ab,kf. (7311)
3 ((pressure or deep tissue$) adj5 (sore$ or injur$ or lesion$)).ti,ab,kf. (8394)
4 decubit$.ti,ab,kf. (5140)
5 (bedsore$ or bed-sore$).ti,ab,kf. (651)
6 or/1-5 (22928)
7 exp Bandages/ (22641)
8 (bandage$ or dressing$).ti,ab,kf. (24510)
9 (layer or layers).ti,ab,kf. (331738)
10 or/7-9 (367991)
11 Polyurethanes/ (8640)
12 exp Silicones/ (25525)
13 (foam$ or silicon$ or polyurethan$ or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1).ti,ab,kf,rn,nm. (142170)
14 or/11-13 (145343)
15 6 and 10 and 14 (210)
16 6 and 10 and (Shear Strength/ or shear.ti,ab,kf.) (63)
17 Mepilex$2.af. (62)
18 Safetac$2.af. (16)
19 M?lnlycke$2.af. (145)
20 (5-layer$ or five-layer$ or 3-layer$ or three-layer$).ti,ab,kf. (6048)
21 (multi-layer$ or multilayer$).ti,ab,kf. (25630)
22 soft silicon$.ti,ab,kf. (260)
23 (silicon$ adj5 foam$).ti,ab,kf. (188)
24 ((foam$ or silicon$ or polyurethan$) adj5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)).ti,ab,kf. (429)
25 or/17-24 (32215)
26 6 and 25 (102)
27 Mepilex$2 Border$2.af. (16)

28 15 or 16 or 26 or 27 (302)
29 exp animals/ not humans/ (4436130)
30 28 not 29 (288)
31 limit 30 to yr="2001 -Current" (236)
32 remove duplicates from 31 (236)

2: Source: Embase 1974 to 2018 March 26

Interface / URL: OvidSP

Database coverage dates: 1974 to 2018 March 26

Search date: 27/03/18

Retrieved records: 370

Search strategy:

1 decubitus/ (18794)
2 ((pressure or deep tissue$) adj5 ulcer$).ti,ab,kw. (9135)
3 ((pressure or deep tissue$) adj5 (sore$ or injur$ or lesion$)).ti,ab,kw. (10716)
4 decubit$.ti,ab,kw. (7234)
5 (bedsore$ or bed-sore$).ti,ab,kw. (1006)
6 or/1-5 (31805)
7 "bandages and dressings"/ or exp bandage/ or exp wound dressing/ (29669)
8 (bandage$ or dressing$).ti,ab,kw. (30763)
9 (layer or layers).ti,ab,kw. (352507)
10 or/7-9 (397627)
11 foam/ or polyurethan foam/ or polyurethan/ (18439)
12 silicone/ or silicone derivative/ (19094)
13 (foam$ or silicon$ or polyurethan$ or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1).ti,ab,kw,rn. (158408)
14 or/11-13 (161309)
15 6 and 10 and 14 (288)
16 6 and 10 and (shear strength/ or shear stress/ or shear.ti,ab,kw.) (78)
17 foam dressing/ (742)
18 silicone dressing/ (74)
19 Mepilex$2.af. (231)
20 Safetac$2.af. (31)
21 M?lnlycke$2.af. (517)
22 (5-layer$ or five-layer$ or 3-layer$ or three-layer$).ti,ab,kw. (6505)
23 (multi-layer$ or multilayer$).ti,ab,kw. (22676)
24 soft silicon$.ti,ab,kw. (363)
25 (silicon$ adj5 foam$).ti,ab,kw. (246)

26 ((foam$ or silicon$ or polyurethan$) adj5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)).ti,ab,kw. (529)
27 or/17-26 (31017)
28 6 and 27 (202)
29 Mepilex$2 Border$2.af. (50)
30 15 or 16 or 28 or 29 (473)
31 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (5835134)
32 30 not 31 (456)
33 limit 32 to yr="2001 -Current" (383)
34 remove duplicates from 33 (370)

3: Source: Science Citation Index Expanded (SCI-EXPANDED) - 1900-present / Conference Proceedings Citation Index- Science (CPCI-S) - 1990-present

Interface / URL: Web of Science
Database coverage dates: 1900 - present (SCI); 1990 – present (CPCI-S)
Search date: 27/03/18
Retrieved records: 218
Search strategy:

Indexes=SCI-EXPANDED, CPCI-S Timespan=All years

24 218 #23 Timespan=2001-2018

23 234 #10 or #11 or #21 or #22

22 10 TS="Mepilex* Border*"

21 116 #5 and #20

20 203,064 #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19

19 1,579 TS=((foam* or silicon* or polyurethan*) near/5 ("adherent" or "nonadherent" or "selfadherent" or "adhesive" or "nonadhesive" or "selfadhesive"))

18 714 TS=(silicon* near/5 foam*)

17 342 TS="soft silicon*"

# 16	175,015	TS=(multi-layer* or multilayer*)
# 15	28,601	TS=(5-layer* or five-layer* or 3-layer* or three-layer*)
# 14	297	TS=M?lnlycke* or AD=M?lnlycke* or OG=M?lnlycke* or OO=M?lnlycke* or SG=M?lnlycke* or FO=M?lnlycke*
# 13	7	TS=Safetac*
# 12	50	TS=Mepilex*
# 11	54	#5 and #8 and TS="shear"
# 10	140	#5 and #8 and #9
# 9	647,781	TS=(foam* or silicon* or polyurethan* or "9009-54-5" or "63148-53-8" or "8043-93-4" or "8055-24-1")
# 8	1,487,083	#6 or #7
# 7	1,460,316	TS=("layer" or "layers")
# 6	27,879	TS=(bandage* or dressing*)
# 5	16,448	#1 or #2 or #3 or #4
# 4	401	TS=(bedsore* or bed-sore*)
# 3	3,425	TS=decubit*
# 2	7,624	TS=(("pressure" or "deep tissue*") near/5 (sore* or injur* or lesion*))
# 1	6,632	TS=(("pressure" or "deep tissue*") near/5 ulcer*)

4: Source: CINAHL Plus

Interface / URL: EBSCOhost

Database coverage dates: Information not found

Search date: 27/03/18

Retrieved records: 288

Search strategy:

S29 S28 Published Date: 20010101-20181231 (288)

S28 S15 OR S16 OR S26 OR S27 (316)

S27 TX("Mepilex* Border*") (20)

S26 S6 AND S25 (194)

S25 S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 (2,243)

S24 TI((foam* or silicon* or polyurethan*) N5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)) or AB((foam* or silicon* or polyurethan*) N5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)) (125)

S23 TI(silicon* N5 foam*) or AB(silicon* N5 foam*) (79)

S22 TI("soft silicon*") or AB("soft silicon*") (99)

S21 TI(multi-layer* or multilayer*) or AB(multi-layer* or multilayer*) (953)

S20 TI(5-layer* or five-layer* or 3-layer* or three-layer*) or AB(5-layer* or five-layer* or 3-layer* or three-layer*) (282)

S19 TX(Molnlycke*) (141)

S18 TX(Safetac*) (21)

S17 TX(Mepilex*) or (MH "Foam Dressings") (772)

S16 S6 AND S10 AND ((MH "Shear") or TI(shear) OR AB(shear)) (48)

S15 S6 AND S10 AND S14 (184)

S14 S11 OR S12 OR S13 (7,313)

S13 TI(foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1) or AB(foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1) (6,143)

S12 (MH "Silicones+") (1,956)

S11 (MH "Polyurethanes") (659)

S10 S7 OR S8 OR S9 (24,643)

S9 TI(layer or layers) or AB(layer or layers) (9,371)

S8 TI(bandage* or dressing*) or AB(bandage* or dressing*) (8,908)

S7 (MH "Bandages and Dressings+") (11,648)

S6 S1 OR S2 OR S3 OR S4 OR S5 (15,157)

S5 TI(bedsore* or bed-sore*) or AB(bedsore* or bed-sore*) (238)

S4 TI(decubit*) OR AB(decubit*) (964)

S3 TI((pressure or "deep tissue*") N5 (sore* or injur* or lesion*)) or AB((pressure or "deep tissue*") N5 (sore* or injur* or lesion*)) (3,702)

S2 TI((pressure or "deep tissue*") N5 ulcer*) or AB((pressure or "deep tissue*") N5 ulcer*) (7,155)

S1 (MH "Pressure Ulcer+") (11,558)

5: Source: British Nursing Index

Interface / URL: ProQuest

Database coverage dates: Information not found

Search date: 27/03/18

Retrieved records: 126

Search strategy:

S1 MAINSUBJECT.EXACT("Pressure ulcers") 3961°

S2 TI,AB((pressure or "deep tissue*") near/5 ulcer*) 3648°

S3 TI,AB((pressure or "deep tissue*") near/5 (sore* or injur* or lesion*)) 1575°

S4 TI,AB(decubit*) 73°

S5 TI,AB(bedsore* or bed-sore*) 42°

S6 S1 OR S2 OR S3 OR S4 OR S5 5387°

S7 MAINSUBJECT.EXACT("Medical dressings") 3080°

S8 TI,AB(bandage* or dressing*) 3599°

S9 TI,AB(layer or layers) 777°

S10 S7 OR S8 OR S9 5320°

S11 MAINSUBJECT.EXACT("Polyurethane") 7°

S12 MAINSUBJECT.EXACT("Silicones") 52°

S13 MAINSUBJECT.EXACT("Plastic foams") OR MAINSUBJECT.EXACT("Polystyrene foams") 1°

S14 TI,AB(foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1) 818°

S15 S11 OR S12 OR S13 OR S14 823°

S16 S6 AND S10 AND S15 88°

S17 S10 AND S6 AND (MAINSUBJECT.EXACT("Shear loading") OR MAINSUBJECT.EXACT("Shear strength") OR MAINSUBJECT.EXACT("Shear strain") OR MAINSUBJECT.EXACT("Shear stresses") OR TI,AB(shear)) 22°

S18 Mepilex* 70°

S19 Safetac* 51°

S20 M?lnlycke* 178°

S21 TI,AB(5-layer* or five-layer* or 3-layer* or three-layer*) 22°

S22 TI,AB(multi-layer* or multilayer*) 182°

S23 TI,AB("soft silicon*") 47°

S24 TI,AB(silicon* near/5 foam*) 38°

S25 TI,AB((foam* or silicon* or polyurethan*) near/5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)) 84°

S26 S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 543°

S27 S6 AND S26 60°

S28 "Mepilex* Border*" 26°

S29 S16 OR S17 OR S27 OR S28 145°

S30 (S16 OR S17 OR S27 OR S28) AND pd(20010101-20181231) 133°

Duplicates are removed from your search and from your result count.

Note: the final line (S30) gives the total number of results returned as 133. On attempting to download the results, only 126 were available to download. The search was re-run several times with the same outcome, with the final line figure changing each time the searcher returned from the results page to the search history page. Only 126 records were retrieved.

6: Source: Cochrane Central Register of Controlled Trials: Issue 2 of 12, February 2018

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found

Search date: 28/03/18

Retrieved records: 75

Search strategy:

#1 [mh ^"Pressure Ulcer"] 707

#2 ((pressure or deep next tissue*) near/5 ulcer*) 1394

#3 ((pressure or deep next tissue*) near/5 (sore* or injur* or lesion*)) 1298

#4 decubit* 970

#5 (bedsore* or bed-sore*) 109

#6 #1 or #2 or #3 or #4 or #5 3048

#7 [mh Bandages] 2806

#8 (bandage* or dressing*) 6193

#9 (layer or layers) 4419

#10 #7 or #8 or #9 10559

#11 [mh ^Polyurethanes] 429

#12 [mh Silicones] 940

#13 (foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1) 5312

#14 #11 or #12 or #13 5450

#15 #6 and #10 and #14 144

#16 #6 and #10 and ([mh ^"Shear Strength"] or shear) 41

#17 Mepilex* 48

#18 Safetac* 3

#19 M?lnlycke* 58

#20 (5-layer* or five-layer* or 3-layer* or three-layer*) 111

#21 (multi-layer* or multilayer*) 262

#22 (soft next silicon*) 79

#23 (silicon* near/5 foam*) 37

#24 ((foam* or silicon* or polyurethan*) near/5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)) 119

#25 #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 593

#26 #6 and #25 75
#27 (Mepilex* next Border*) 15
#28 #15 or #16 or #26 or #27 192
#29 #28 Publication Year from 2001 to 2018 171
#30 #29 in Trials75

7: Source: Database of Abstracts of Reviews of Effects: Issue 2 of 4, April 2015

Interface / URL: Cochrane Library / Wiley
Database coverage dates: Information not found. Bibliographic records were published on DARE until 31st March 2015. Searches for content were conducted up until the end of December 2014.
Search date: 28/03/18
Retrieved records: 7
Search strategy:

#1 [mh ^"Pressure Ulcer"] 707
#2 ((pressure or deep next tissue*) near/5 ulcer*) 1394
#3 ((pressure or deep next tissue*) near/5 (sore* or injur* or lesion*)) 1298
#4 decubit* 970
#5 (bedsore* or bed-sore*) 109
#6 #1 or #2 or #3 or #4 or #5 3048
#7 [mh Bandages] 2806
#8 (bandage* or dressing*) 6193
#9 (layer or layers) 4419
#10 #7 or #8 or #9 10559
#11 [mh ^Polyurethanes] 429
#12 [mh Silicones] 940
#13 (foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1) 5312
#14 #11 or #12 or #13 5450
#15 #6 and #10 and #14 144
#16 #6 and #10 and ([mh ^"Shear Strength"] or shear) 41
#17 Mepilex* 48
#18 Safetac* 3
#19 M?lnlycke* 58
#20 (5-layer* or five-layer* or 3-layer* or three-layer*) 111
#21 (multi-layer* or multilayer*) 262
#22 (soft next silicon*) 79
#23 (silicon* near/5 foam*) 37

#24 ((foam* or silicon* or polyurethan*) near/5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)) 119
#25 #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 593
#26 #6 and #25 75
#27 (Mepilex* next Border*) 15
#28 #15 or #16 or #26 or #27 192
#29 #28 Publication Year from 2001 to 2018 171
#30 #29 in Trials75
#31 #29 in Other Reviews 7

8: Source: NHS Economic Evaluation Database: Issue 2 of 4, April 2015

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Bibliographic records were published on NHS EED until 31st March 2015. Searches for content were conducted up until the end of December 2014.

Search date: 28/03/18

Retrieved records: 5

Search strategy:

#1 [mh ^"Pressure Ulcer"] 707
#2 ((pressure or deep next tissue*) near/5 ulcer*) 1394
#3 ((pressure or deep next tissue*) near/5 (sore* or injur* or lesion*)) 1298
#4 decubit* 970
#5 (bedsore* or bed-sore*) 109
#6 #1 or #2 or #3 or #4 or #5 3048
#7 [mh Bandages] 2806
#8 (bandage* or dressing*) 6193
#9 (layer or layers) 4419
#10 #7 or #8 or #9 10559
#11 [mh ^Polyurethanes] 429
#12 [mh Silicones] 940
#13 (foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1) 5312
#14 #11 or #12 or #13 5450
#15 #6 and #10 and #14 144
#16 #6 and #10 and ([mh ^"Shear Strength"] or shear) 41
#17 Mepilex* 48
#18 Safetac* 3
#19 M?lnlycke* 58
#20 (5-layer* or five-layer* or 3-layer* or three-layer*) 111

#21 (multi-layer* or multilayer*) 262
#22 (soft next silicon*) 79
#23 (silicon* near/5 foam*) 37
#24 ((foam* or silicon* or polyurethan*) near/5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)) 119
#25 #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 593
#26 #6 and #25 75
#27 (Mepilex* next Border*) 15
#28 #15 or #16 or #26 or #27 192
#29 #28 Publication Year from 2001 to 2018 171
#30 #29 in Trials75
#31 #29 in Other Reviews 7
#32 #29 in Economic Evaluations 5

9: Source: Cochrane Database of Systematic Reviews: Issue 3 of 12, March 2018

Interface / URL: Cochrane Library / Wiley
Database coverage dates: Information not found
Search date: 28/03/18
Retrieved records: 17
Search strategy:

#1 [mh ^"Pressure Ulcer"] 707
#2 ((pressure or deep next tissue*) near/5 ulcer*):ti,ab,kw 1230
#3 ((pressure or deep next tissue*) near/5 (sore* or injur* or lesion*)):ti,ab,kw 1102
#4 decubit*:ti,ab,kw 851
#5 (bedsore* or bed-sore*):ti,ab,kw 69
#6 #1 or #2 or #3 or #4 or #5 2694
#7 [mh Bandages] 2806
#8 (bandage* or dressing*):ti,ab,kw 5555
#9 (layer or layers):ti,ab,kw 3686
#10 #7 or #8 or #9 9359
#11 [mh ^Polyurethanes] 429
#12 [mh Silicones] 940
#13 (foam* or silicon* or polyurethan* or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1):ti,ab,kw 4815
#14 #11 or #12 or #13 4954
#15 #6 and #10 and #14 78
#16 #6 and #10 and ([mh ^"Shear Strength"] or shear:ti,ab,kw) 13
#17 Mepilex* 48
#18 Safetac* 3

#19 M?lnlycke* 58
#20 (5-layer* or five-layer* or 3-layer* or three-layer*):ti,ab,kw 77
#21 (multi-layer* or multilayer*):ti,ab,kw 210
#22 (soft next silicon*):ti,ab,kw 54
#23 (silicon* near/5 foam*):ti,ab,kw 31
#24 ((foam* or silicon* or polyurethan*) near/5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)):ti,ab,kw 80
#25 #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 493
#26 #6 and #25 40
#27 (Mepilex* next Border*) 15
#28 #15 or #16 or #26 or #27 110
#29 #28 Publication Year from 2001 to 2018 95
#30 #29 in Cochrane Reviews (Reviews and Protocols) 17

10: Source: Health Technology Assessment Database

Interface / URL: https://www.crd.york.ac.uk/CRDWeb/

Database coverage dates: Information not found

Search date: 29/03/18

Retrieved records: 21

Search strategy:

1 MeSH DESCRIPTOR Pressure Ulcer 169
2 (((pressure or deep tissue*) NEAR5 ulcer*)) 264
3 ((ulcer* NEAR5 (pressure or deep tissue*))) 71
4 (((pressure or deep tissue*) NEAR5 (sore* or injur* or lesion*))) 85
5 ((sore* or injur* or lesion*) NEAR5 (pressure or deep tissue*)) 30
6 (decubit*) 23
7 ((bedsore* or bed-sore*)) 7
8 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 349
9 MeSH DESCRIPTOR Bandages EXPLODE ALL TREES 300
10 ((bandage* or dressing*)) 546
11 ((layer or layers)) 123
12 #9 OR #10 OR #11 675
13 #8 AND #1298
14 (Mepilex*) 1
15 (Safetac*) 0
16 (Molnlycke*) 1
17 ((5-layer* or five-layer* or 3-layer* or three-layer*)) 2

18 ((multi-layer* or multilayer*)) 8
19 (soft silicon*) 5
20 ((silicon* NEAR5 foam*)) 2
21 ((foam* NEAR5 silicon*)) 0
22 (((foam* or silicon* or polyurethan*) NEAR5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive))) 3

23 (((adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive) NEAR5 (foam* or silicon* or polyurethan*))) 4

24 #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 24
25 #8 AND #245
26 (Mepilex* Border*) 1
27 #13 OR #25 OR #26 99
28 (#27) IN HTA FROM 2001 TO 2018 21

11: Source: PubMed

Interface / URL: https://www.ncbi.nlm.nih.gov/pubmed/
Database coverage dates: Information not found
Search date: 29/03/18
Retrieved records: 55
Search strategy:

#33 Search (#31 NOT #32) 55
#32 Search medline[sb] 24790847
#31 Search (#28 NOT #29) Filters: Publication date from 2001/01/01 to 2018/12/31 292
#30 Search (#28 NOT #29) 357
#29 Search animals [mh] NOT humans [mh:noexp] 4438294
#28 Search (#15 OR #16 OR #26 OR #27) 369
#27 Search Mepilex*[All Fields] AND Border*[All Fields] 19
#26 Search (#6 AND #25) 158
#25 Search (#17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24) 33757
#24 Search ((foam*[tiab] OR silicon*[tiab] OR polyurethan*[tiab]) AND (adherent[tiab] OR nonadherent[tiab] OR selfadherent[tiab] OR adhesive[tiab] OR nonadhesive[tiab] OR selfadhesive[tiab])) 1859
#23 Search (silicon*[tiab] AND foam*[tiab]) 359
#22 Search soft silicon*[tiab] 245

#21 Search (multi-layer*[tiab] OR multilayer*[tiab]) 25622
#20 Search (5-layer*[tiab] OR five-layer*[tiab] OR 3-layer*[tiab] OR three-layer*[tiab]) 6059
#19 Search Molnlycke*[All Fields] 144
#18 Search Safetac*[All Fields] 16
#17 Search mepilex*[All Fields] 62
#16 Search #6 AND #10 AND (Shear Strength[mh:noexp] OR shear[tiab]) 67
#15 Search #6 AND #10 AND #14 240
#14 Search (#11 OR #12 OR #13) 115393
#13 Search ((foam*[tiab] OR foam*[rn] OR foam*[nm]) OR (silicon*[tiab] OR silicon*[rn] OR silicon*[nm]) OR (polyurethan*[tiab] OR polyurethan*[rn] OR polyurethan*[nm]) OR (9009-54-5[tiab] OR 9009-54-5[rn] OR 9009-54-5[nm]) OR (63148-53-8[tiab] OR 63148-53-8[rn] OR 63148-53-8[nm]) OR (8043-93-4[tiab] OR 8043-93-4[rn] OR 8043-93-4[nm]) OR (8055-24-1[tiab] OR 8055-24-1[rn] OR 8055-24-1[nm])) 108166
#12 Search Silicones[mh] 25533
#11 Search Polyurethanes[mh:noexp] 8643
#10 Search (#7 OR #8 OR #9) 367855
#9 Search (layer[tiab] OR layers[tiab]) 331608
#8 Search (bandage*[tiab] OR dressing*[tiab]) 24501
#7 Search Bandages[mh] 22654
#6 Search (#1 OR #2 OR #3 OR #4 OR #5) 22212
#5 Search (bedsore*[tiab] OR bed-sore*[tiab]) 650
#4 Search decubit*[tiab] 5118
#3 Search (pressure sore*[tiab] OR pressure injur*[tiab] OR pressure lesion*[tiab]) OR (deep tissue*[tiab] AND (sore*[tiab] OR injur*[tiab] OR lesion*[tiab])) 4012
#2 Search ((pressure[tiab] OR deep tissue*[tiab]) AND ulcer*[tiab]) 11033
#1 Search Pressure Ulcer [mh:noexp] 11247

12: Source: Econlit 1886 to March 22, 2018

Interface / URL: OvidSP

Database coverage dates: 1886 to March 22, 2018

Search date: 29/03/18

Retrieved records: 0

Search strategy:

1 ((pressure or deep tissue$) adj5 ulcer$).af. (14)
2 ((pressure or deep tissue$) adj5 (sore$ or injur$ or lesion$)).af. (5)

3 decubit$.af. (0)
4 (bedsore$ or bed-sore$).af. (1)
5 or/1-4 (20)
6 (bandage$ or dressing$).af. (181)
7 (layer or layers).af. (1170)
8 or/6-7 (1351)
9 (foam$ or silicon$ or polyurethan$ or 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1).af. (500)
10 5 and 8 and 9 (0)
11 5 and 8 and shear.af. (0)
12 Mepilex$2.af. (0)
13 Safetac$2.af. (0)
14 M?lnlycke$2.af. (0)
15 (5-layer$ or five-layer$ or 3-layer$ or three-layer$).af. (73)
16 (multi-layer$ or multilayer$).af. (426)
17 soft silicon$.af. (0)
18 (silicon$ adj5 foam$).af. (0)
19 ((foam$ or silicon$ or polyurethan$) adj5 (adherent or nonadherent or selfadherent or adhesive or nonadhesive or selfadhesive)).af. (0)
20 or/12-19 (495)
21 5 and 20 (0)
22 Mepilex$2 Border$2.af. (0)
23 10 or 11 or 21 or 22 (0)
24 limit 23 to yr="2001 -Current" (0)

13: Source: ClinicalTrials.gov

Interface / URL: https://clinicaltrials.gov/ct2/home
Database coverage dates: Information not found
Search date: 29/03/18
Retrieved records: 227
Search strategy:

The following 13 searches were conducted separately in the Expert interface. Results were downloaded separately.

1. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (bandage OR bandages OR bandaged OR dressing OR dressings OR layer OR layers) AND (foam OR foams OR silicon OR silicons OR silicone OR silicones OR polyurethan OR polyurethans OR

polyurethane OR polyurethanes OR 9009-54-5 OR 63148-53-8 OR 8043-93-4 OR 8055-24-1 OR shear) = 63

2. (decubitus OR decubital) AND (bandage OR bandages OR bandaged OR dressing OR dressings OR layer OR layers) AND (foam OR foams OR silicon OR silicons OR silicone OR silicones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes OR 9009-54-5 OR 63148-53-8 OR 8043-93-4 OR 8055-24-1 OR shear) = 23

3. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (bandage OR bandages OR bandaged OR dressing OR dressings OR layer OR layers) AND (foam OR foams OR silicon OR silicons OR silicone OR silicones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes OR 9009-54-5 OR 63148-53-8 OR 8043-93-4 OR 8055-24-1 OR shear) = 23

4. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (Mepilex OR MepilexR OR MepilexTM OR Safetac OR SafetacR OR SafetacTM OR Molnlycke OR MolnlyckeR OR MolnlyckeTM OR 5-layer OR five-layer OR 3-layer OR three-layer OR 5-layers OR five-layers OR 3-layers OR three-layers OR 5-layered OR five-layered OR 3-layered OR three-layered OR multi-layer OR multilayer OR multi-layers OR multilayers OR multi-layered OR multilayered OR "soft silicon" OR "soft silicons" OR "soft silicone" OR "soft silicones") = 29

5. (decubitus OR decubital) AND (Mepilex OR MepilexR OR MepilexTM OR Safetac OR SafetacR OR SafetacTM OR Molnlycke OR MolnlyckeR OR MolnlyckeTM OR 5-layer OR five-layer OR 3-layer OR three-layer OR 5-layers OR five-layers OR 3-layers OR three-layers OR 5-layered OR five-layered OR 3-layered OR three-layered OR multi-layer OR multilayer OR multi-layers OR multilayers OR multi-layered OR multilayered OR "soft silicon" OR "soft silicons" OR "soft silicone" OR "soft silicones") = 14

6. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (Mepilex OR MepilexR OR MepilexTM OR Safetac OR SafetacR OR SafetacTM OR Molnlycke OR MolnlyckeR OR MolnlyckeTM OR 5-layer OR five-layer OR 3-layer OR three-layer OR 5-layers OR five-layers OR 3-layers OR three-layers OR 5-layered OR five-layered OR 3-layered OR three-layered OR multi-layer OR multilayer OR multi-layers OR multilayers OR multi-layered OR multilayered OR "soft silicon" OR "soft silicons" OR "soft silicone" OR "soft silicones") = 14

7. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (silicon OR silicons OR silicone OR silcones) AND (foam OR foams) = 3

8. (decubitus OR decubital) AND (silicon OR silicons OR silicone OR silcones) AND (foam OR foams) = 1

9. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (silicon OR silicons OR silicone OR silcones) AND (foam OR foams) = 1

10. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (foam OR foams OR silicon OR silicons OR silicone OR silcones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes) AND (adherent OR nonadherent OR selfadherent OR adhesive OR nonadhesive OR selfadhesive) = 20

11. (decubitus OR decubital) AND (foam OR foams OR silicon OR silicons OR silicone OR silcones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes) AND (adherent OR nonadherent OR selfadherent OR adhesive OR nonadhesive OR selfadhesive) = 8

12. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (foam OR foams OR silicon OR silicons OR silicone OR silcones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes) AND (adherent OR nonadherent OR selfadherent OR adhesive OR nonadhesive OR selfadhesive) = 8

13. (Mepilex OR MepilexR OR MepilexTM) AND (Border OR BorderR OR BorderTM) = 20

14: Source: WHO International Clinical Trials Registry Platform (ICTRP)

Interface / URL: http://apps.who.int/trialsearch/Default.aspx
Database coverage dates: Information not found
Search date: 29/03/18
Retrieved records: 207
Search strategy:

The following 9 searches were carried out separately, using the search interface at: http://apps.who.int/trialsearch/Default.aspx. Results were downloaded separately.

1. ulcer* AND foam* OR ulcer* AND silicon* OR ulcer* AND polyurethan* OR ulcer* AND shear OR ulcer* AND Mepilex* OR ulcer* AND Safetac* OR ulcer* AND Molnlycke* OR ulcer* AND 5-layer* OR ulcer* AND five-layer* OR ulcer* AND 3-layer* OR ulcer* AND three-layer* OR ulcer* AND 5 layer* OR ulcer* AND five layer* OR ulcer* AND 3 layer* OR ulcer* AND three layer* OR ulcer* AND multi-layer* OR ulcer* AND multi layer* OR ulcer* AND multilayer* = 89 (96 records for 89 trials)

2. sore* AND foam* OR sore* AND silicon* OR sore* AND polyurethan* OR sore* AND shear OR sore* AND Mepilex* OR sore* AND Safetac* OR sore* AND Molnlycke* OR sore* AND 5-layer* OR sore* AND five-layer* OR sore* AND 3-layer* OR sore* AND three-layer* OR sore* AND 5 layer* OR sore* AND five layer* OR sore* AND 3 layer* OR sore* AND three layer* OR sore* AND multi-layer* OR sore* AND multi layer* OR sore* AND multilayer* = 7 (7 records for 7 trials found)

3. injur* AND foam* OR injur* AND silicon* OR injur* AND polyurethan* OR injur* AND shear OR injur* AND Mepilex* OR injur* AND Safetac* OR injur* AND Molnlycke* OR injur* AND 5-layer* OR injur* AND five-layer* OR injur* AND 3-layer* OR injur* AND three-layer* OR injur* AND 5 layer* OR injur* AND five layer* OR injur* AND 3 layer* OR injur* AND three layer* OR injur* AND multi-layer* OR injur* AND multi layer* OR injur* AND multilayer* = 56 (56 records for 56 trials found)

4. lesion* AND foam* OR lesion* AND silicon* OR lesion* AND polyurethan* OR lesion* AND shear OR lesion* AND Mepilex* OR lesion* AND Safetac* OR lesion* AND Molnlycke* OR lesion* AND 5-layer* OR lesion* AND five-layer* OR lesion* AND 3-layer* OR lesion* AND three-layer* OR lesion* AND 5 layer* OR lesion* AND five layer* OR lesion* AND 3 layer* OR lesion* AND three layer* OR lesion* AND multi-layer* OR lesion* AND multi layer* OR lesion* AND multilayer* = 29 (29 records for 29 trials)

5. decubit* AND foam* OR decubit* AND silicon* OR decubit* AND polyurethan* OR decubit* AND shear OR decubit* AND Mepilex* OR decubit* AND Safetac* OR decubit* AND Molnlycke* OR decubit* AND 5-layer* OR decubit* AND five-layer* OR decubit* AND 3-layer* OR decubit* AND three-layer* OR decubit* AND 5 layer* OR decubit* AND five layer* OR decubit* AND

3 layer* OR decubit* AND three layer* OR decubit* AND multi-layer* OR decubit* AND multi layer* OR decubit* AND multilayer* = 6 (6 records for 6 trials found)

6. bedsore* AND foam* OR bedsore* AND silicon* OR bedsore* AND polyurethan* OR bedsore* AND shear OR bedsore* AND Mepilex* OR bedsore* AND Safetac* OR bedsore* AND Molnlycke* OR bedsore* AND 5-layer* OR bedsore* AND five-layer* OR bedsore* AND 3-layer* OR bedsore* AND three-layer* OR bedsore* AND 5 layer* OR bedsore* AND five layer* OR bedsore* AND 3 layer* OR bedsore* AND three layer* OR bedsore* AND multi-layer* OR bedsore* AND multi layer* OR bedsore* AND multilayer* = 3 (3 records for 3 trials)

7. bed-sore* AND foam* OR bed-sore* AND silicon* OR bed-sore* AND polyurethan* OR bed-sore* AND shear OR bed-sore* AND Mepilex* OR bed-sore* AND Safetac* OR bed-sore* AND Molnlycke* OR bed-sore* AND 5-layer* OR bed-sore* AND five-layer* OR bed-sore* AND 3-layer* OR bed-sore* AND three-layer* OR bed-sore* AND 5 layer* OR bed-sore* AND five layer* OR bed-sore* AND 3 layer* OR bed-sore* AND three layer* OR bed-sore* AND multi-layer* OR bed-sore* AND multi layer* OR bed-sore* AND multilayer* = 0

8. 9009-54-5 or 63148-53-8 or 8043-93-4 or 8055-24-1 = 0

9. Mepilex* AND Border* = 17 (17 records for 17 trials found)

15: Source: ISRCTN Registry
Interface / URL: https://www.isrctn.com/
Database coverage dates: Information not found
Search date: 29/03/18
Retrieved records: 8
Search strategy:

The following 13 searches were carried out separately, using the homepage search interface. For each search, only results which were not already retrieved by a previous ISRCTN search were retrieved.

1. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (bandage OR bandages OR bandaged OR dressing OR dressings OR layer OR layers) AND (foam OR foams OR silicon OR silicons OR silicone OR silicones OR polyurethan OR polyurethans OR

polyurethane OR polyurethanes OR 9009-54-5 OR 63148-53-8 OR 8043-93-4 OR 8055-24-1 OR shear) = 6 (6 results returned)

2. (decubitus OR decubital) AND (bandage OR bandages OR bandaged OR dressing OR dressings OR layer OR layers) AND (foam OR foams OR silicon OR silicons OR silicone OR silicones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes OR 9009-54-5 OR 63148-53-8 OR 8043-93-4 OR 8055-24-1 OR shear) = 0 (0 results returned)

3. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (bandage OR bandages OR bandaged OR dressing OR dressings OR layer OR layers) AND (foam OR foams OR silicon OR silicons OR silicone OR silicones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes OR 9009-54-5 OR 63148-53-8 OR 8043-93-4 OR 8055-24-1 OR shear) = 0 (1 result returned, excluded as duplicate)

4. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (Mepilex OR MepilexR OR MepilexTM OR Safetac OR SafetacR OR SafetacTM OR Molnlycke OR MolnlyckeR OR MolnlyckeTM OR 5-layer OR five-layer OR 3-layer OR three-layer OR 5-layers OR five-layers OR 3-layers OR three-layers OR 5-layered OR five-layered OR 3-layered OR three-layered OR multi-layer OR multilayer OR multi-layers OR multilayers OR multi-layered OR multilayered OR "soft silicon" OR "soft silicons" OR "soft silicone" OR "soft silicones") = 2 (3 results returned, 1 excluded as duplicate)

5. (decubitus OR decubital) AND (Mepilex OR MepilexR OR MepilexTM OR Safetac OR SafetacR OR SafetacTM OR Molnlycke OR MolnlyckeR OR MolnlyckeTM OR 5-layer OR five-layer OR 3-layer OR three-layer OR 5-layers OR five-layers OR 3-layers OR three-layers OR 5-layered OR five-layered OR 3-layered OR three-layered OR multi-layer OR multilayer OR multi-layers OR multilayers OR multi-layered OR multilayered OR "soft silicon" OR "soft silicons" OR "soft silicone" OR "soft silicones") = 0 (0 results returned)

6. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (Mepilex OR MepilexR OR MepilexTM OR Safetac OR SafetacR OR SafetacTM OR Molnlycke OR MolnlyckeR OR MolnlyckeTM OR 5-layer OR five-layer OR 3-layer OR three-layer OR 5-layers OR five-layers OR 3-layers OR three-layers OR 5-layered OR five-layered OR 3-layered OR three-layered OR multi-layer OR multilayer OR multi-layers OR multilayers OR multi-layered OR

multilayered OR "soft silicon" OR "soft silicons" OR "soft silicone" OR "soft silicones") = 0 (0 results returned)

7. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (silicon OR silicons OR silicone OR silcones) AND (foam OR foams) = 0 (1 result returned, excluded as duplicate)

8. (decubitus OR decubital) AND (silicon OR silicons OR silicone OR silcones) AND (foam OR foams) = 0 (0 results returned)

9. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (silicon OR silicons OR silicone OR silcones) AND (foam OR foams) = 0 (0 results returned)

10. (pressure OR "deep tissue" OR "deep tissues") AND (ulcer OR ulcers OR ulceration OR ulcerations OR sore or sores OR injury OR injuries OR injured OR lesion OR lesions) AND (foam OR foams OR silicon OR silicons OR silicone OR silcones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes) AND (adherent OR nonadherent OR selfadherent OR adhesive OR nonadhesive OR selfadhesive) = 0 (1 result returned, excluded as duplicate)

11. (decubitus OR decubital) AND (foam OR foams OR silicon OR silicons OR silicone OR silcones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes) AND (adherent OR nonadherent OR selfadherent OR adhesive OR nonadhesive OR selfadhesive) = 0 (0 results returned)

12. (bedsore OR bedsores OR bed-sore OR bed-sores) AND (foam OR foams OR silicon OR silicons OR silicone OR silcones OR polyurethan OR polyurethans OR polyurethane OR polyurethanes) AND (adherent OR nonadherent OR selfadherent OR adhesive OR nonadhesive OR selfadhesive) = 0 (0 results returned)

13. (Mepilex OR MepilexR OR MepilexTM) AND (Border OR BorderR OR BorderTM) = 0 (0 results returned)

16: Source: Cost-Effectiveness Analysis (CEA) Registry
Interface / URL: https://research.tufts-nemc.org/cear4/
Database coverage dates: Information not found
Search date: 02/04/18
Retrieved records: 14

Search strategy:

Freely available search functionality in CEA Registry is very basic – only single term search is supported. Boolean operators are not available. There is no exporting functionality. As a result:

- The following 9 searches were carried out separately, using the basic interface (http://healtheconomics.tuftsmedicalcenter.org/cear4/SearchingtheCEARegistry/SearchtheCEARegistry.aspx - 'Articles' selected.
- Results were only retrieved if not duplicates of records already retrieved via another source.

1. pressure ulcer = 11
2. pressure sore = 1
3. pressure injur = 0
4. pressure lesion = 0
5. deep tissue = 0 (1 retrieved, excluded as duplicate)
6. decubit = 1
7. bedsore = 0
8. bed-sore = 0
9. mepilex = 1

17: Source: European Pressure Ulcer Advisory Panel Annual Meeting
Interface / URL: See below
Database coverage dates: n/a
Search date: 05/04/18
Retrieved records: 22
Search strategy:

Conference abstracts from the last 3 years (2015 – 2018) were sought.

2018. 20th EPUAP Annual Meeting 2018 will be held in September 2018

2017. 19th EPUAP Annual Meeting 2017 – Belfast, Northern Ireland

The PDF of the Programme and Abstract Book was downloaded: http://epuap2017.org/fileadmin/user_upload/EPUAP/Katalog_EPUAP_2017_FINAL.pdf

The Ctrl-F function was used to search across the PDF on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 9 retrieved
silicon = 3 retrieved
polyurethan = 0 retrieved
Mepilex = 1 retrieved
Safetac = 0 retrieved
lnlycke = 1 retrieved
5-layer = 0 retrieved
5 layer = 0 retrieved
five-layer = 0 retrieved
five layer = 0 retrieved
3-layer = 0 retrieved
3 layer = 0 retrieved
three-layer = 0 retrieved
three layer = 0 retrieved
multi-layer = 0 retrieved
multi layer = 0 retrieved
multilayer = 0 retrieved

13 results retrieved

2016. No meeting held.

2015. 18th EPUAP Annual Meeting 2015 – Ghent, Belgium

The PDF of the Programme and Abstract Book was downloaded: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf

The Ctrl-F function was used to search across the PDF on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved (reports on foam mattresses, cushions, footstools and positioners, and silicone sprays, etc. were not retrieved). Within-set duplicates were not retrieved.

foam = 7 retrieved
silicon = 1 retrieved

polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
5-layer = 0 retrieved
5 layer = 0 retrieved
five-layer = 0 retrieved
five layer = 0 retrieved
3-layer = 0 retrieved
3 layer = 0 retrieved
three-layer = 0 retrieved
three layer = 0 retrieved
multi-layer = 1 retrieved
multi layer = 0 retrieved
multilayer = 0 retrieved

9 results retrieved

18: Source: Symposium on Advanced Wound Care Biannual (Spring / Fall) Event

Interface / URL: See below
Database coverage dates: n/a
Search date: 05/04/18
Retrieved records: 34
Search strategy:

Conference abstracts from the last 3 years (2015 – 2018) were sought.

The EAC was unable to locate full abstracts for the following events: Spring 2018, Fall 2017, Fall 2016, Fall 2015 and Spring 2015.

The Symposium on Advanced Wound Care (SAWC) organisation was contacted (via the SAWC online contact page, and via e-mail to the SAWC Abstract submission team) to enquire about availability of full abstracts for all oral and poster presentations at these events. The organisers replied to confirm that they did not have access to full abstracts, were unable to send them to the EAC, were unable to direct the EAC to any source online, and only distributed abstract materials onsite. The company were also contacted to see if they could provide the abstracts but they were unable to locate or provide access.

2018 Spring: Symposium on Advanced Wound Care Biannual Spring 2018 Event

The 2018 Spring Event will be held on April 25–29, 2018. All accepted oral/poster details for SAWC abstracts have been finalized.

Unable to locate full conference abstracts. A list of titles for accepted posters was found in the following PDF. This is a list of titles only – the full abstract is not provided.
http://www.sawc.net/spring/sites/default/files/Accepted%20SAWC%20Spring%202018%20Abstracts%20-%20Poster%20Abstract%20Web%20Lisitingv%203.22.2018%20-%20With%20Numbers.pdf.

The Ctrl-F function was used to search across the PDF, using the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 15 retrieved
silicon = 5 retrieved
polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
layer = 1 retrieved

21 retrieved

Unable to locate full conference abstracts. A list of titles for accepted oral presentations is found in the following PDF. This is a list of titles only – the full abstract is not provided.
http://www.sawc.net/spring/sites/default/files/Accepted%20SAWC%20Spring%202018%20Abstracts%20-%20Oral%20Web%20Listv%203.12.2018%20-%20With%20Numbers.pdf

The Ctrl-F function was used to search across the PDF using the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 0 retrieved
silicon = 0 retrieved
polyurethan = 0 retrieved

Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
layer = 0 retrieved

0 retrieved

2017 Fall: Symposium on Advanced Wound Care Biannual Fall 2017 Event

Unable to locate full conference abstracts. A list of titles for posters was found in the following PDF:
http://www.sawc.net/fall/sites/default/files/Accepted%20SAWC%20Fall%20Abstracts_2017_New%20as%20of%2010.6.2017%5B1%5D.pdf

The Ctrl-F function was used to search across the PDF using the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 8 retrieved
silicon = 2 retrieved
polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
layer = 0 retrieved

10 retrieved

Unable to locate full conference abstracts. A list of titles for oral presentations is found in the following PDF. This is a list of titles only – the full abstract is not provided:
http://www.sawc.net/fall/sites/default/files/SAWC%20Fall%202017_Accepted%20Oral%20Abstracts_0.pdf

The Ctrl-F function was used to search across the PDF on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 0 retrieved

silicon = 0 retrieved
polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
layer = 0 retrieved

0 retrieved

2017 Spring: Symposium on Advanced Wound Care Biannual Spring 2017 Event

PDF of conference abstracts for 29th Annual Meeting of the Wound Healing Society,SAWC-Spring/WHS Joint MeetingSan Diego Convention Center, San Diego, California, USA, April 5–9, 2017: https://onlinelibrary.wiley.com/doi/epdf/10.1111/wrr.12573

The Ctrl-F function was used to search across the PDF on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 1 retrieved
silicon = 0 retrieved
polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
layer = 0 retrieved

1 retrieved

2016 Fall: Symposium on Advanced Wound Care Biannual Fall 2016 Event

Unable to locate full conference abstracts or titles of abstracts.

2016 Spring: Symposium on Advanced Wound Care Biannual Spring 2016 Event

PDF of conference abstracts for 28th Annual Meeting of the Wound Healing Society,

SAWC-Spring/WHS Joint Meeting, Georgia World Congress Center, Atlanta, Georgia, USA
April 13–17, 2016: https://onlinelibrary.wiley.com/doi/epdf/10.1111/wrr.12405

The Ctrl-F function was used to search across the PDFs on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 2 retrieved
silicon = 0 retrieved
polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
Inlycke = 0 retrieved
layer = 0 retrieved

2 retrieved

2015 Fall: Symposium on Advanced Wound Care Biannual Fall 2015 Event

Unable to locate full conference abstracts or titles of abstracts.

2015 Spring: Symposium on Advanced Wound Care Biannual Spring 2015 Event

Unable to locate full conference abstracts or titles of abstracts.

19: Source: Wound Ostomy and Continence Nurse Annual Conference
Interface / URL: See below
Database coverage dates: n/a
Search date: 05/04/18
Retrieved records: 114
Search strategy:

Conference abstracts from the last 3 years (2015 – 2018) were sought.

2018: WOCN Society's 50th Annual Conference will be held on Sunday, June 3 - Wednesday, June 6, 2018. Accepted abstracts are available to be searched at: https://wocn.confex.com/wocn/2018am/webprogram/start.html

The following searches were conducted ("Any word" selected). All identified individual abstracts were retrieved. Within-set duplicates were not retrieved.

1. foam foams silicon silicons silicone silicones polyurethan polyurethans polyurethane polyurethanes = 37 retrieved

2. Mepilex MepilexR MepilexTM Safetac SafetacR SafetacTM Molnlycke MolnlyckeR MolnlyckeTM Mölnlycke MölnlyckeR MölnlyckeTM = 0 retrieved

3. 5-layer 5-layers 5-layered five-layer five-layers five-layered 3-layer 3-layers 3-layered three-layer three-layers three-layered multi-layer multi-layers multi-layered multilayer
multilayers multilayered = 0 retrieved

4. layer layers layered = 0 retrieved

37 retrieved

2017: 49th Annual Conference (WOCN) - May 19-23, 2017 - Salt Lake City, Utah

Scientific and Clinical Abstracts From the WOCN Society's 49th Annual Conference: Salt Lake City, Utah May 19-23, 2017: https://journals.lww.com/jwocnonline/toc/2017/05001

The Ctrl-F function was used to search across the PDF on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 11 retrieved
silicon = 3 retrieved
polyurethan = 1 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
lnlycke = 0 retrieved
layer = 0 retrieved

15 retrieved

2016: 2016 WOCN Society & CAET Joint Conference - June 4-8, 2016 - Montréal, Québec, Canada

Scientific and Clinical Abstracts From the 2016 WOCN Society & CAET Joint Conference: Montreal, Quebec, Canada June 4-8, 2016: https://journals.lww.com/jwocnonline/toc/2016/05001

The Ctrl-F function was used to search across the PDF on the following terms. The terms were searched individually. All identified presentations and abstracts on dressings judged to be potentially relevant by the searcher were retrieved. Within-set duplicates were not retrieved.

foam = 15 retrieved
silicon = 2 retrieved
polyurethan = 0 retrieved
Mepilex = 0 retrieved
Safetac = 0 retrieved
lnlycke = 0 retrieved
layer = 0 retrieved

17 retrieved

2015: 47th Annual Conference (WOCN) - June 6-10, 2015 - San Antonio, Texas

Database of Accepted Conference Abstracts searched at: https://wocn.confex.com/wocn/2015am/webprogram/start.html

The following searches were conducted ("Any word" selected). All identified individual abstracts were retrieved. Within-set duplicates were not retrieved.

1. foam foams silicon silicons silicone silicones polyurethan polyurethans polyurethane polyurethanes = 40 retrieved

2. Mepilex MepilexR MepilexTM Safetac SafetacR SafetacTM Molnlycke MolnlyckeR MolnlyckeTM Mölnlycke MölnlyckeR MölnlyckeTM = 1 retrieved

3. 5-layer 5-layers 5-layered five-layer five-layers five-layered 3-layer 3-layers 3-layered three-layer three-layers three-layered multi-layer multi-layers multi-layered multilayer multilayers multilayered = 4 retrieved

4. layer layers layered = 0 retrieved

45 retrieved

20: Source: Mölnlycke Health Care UK website pages on Mepilex Border, Mepilex Sacrum and Mepilex Heel

Interface / URL: See below

Database coverage dates: n/a

Search date: 06/04/18

Retrieved records: 16

Search strategy:

The following searches were carried out.

1. Navigated to https://www.molnlycke.co.uk/products-solutions/mepilex-border/ via: Products and solutions / Wound care products / Foam Dressings / Mepilex Border

- Harvested 14 references cited on the page.
- Checked each reference against those retrieved already via other search sources.
- Retrieved all references not identified already via other search sources.

2. Navigated to https://www.molnlycke.co.uk/products-solutions/mepilex-border-sacrum/ via: Products and solutions / Wound care products / Foam Dressings / Mepilex Border /Mepilex Border Sacrum.

- Harvested 12 page references cited on the page.
- Checked each reference against those retrieved already via other search sources.
- Retrieved all references not identified already via other search sources.

3. Navigated to https://www.molnlycke.co.uk/products-solutions/mepilex-border-heel/ via: Products and solutions / Wound care products / Foam Dressings / Mepilex Border / Mepilex Border Heel.

- Harvested 13 page references cited on the page.
- Checked each reference against those retrieved already via other search sources.
- Retrieved all references not identified already via other search sources.

Organisational website searches

The EAC also conducted focused searches of a selection of 63 websites informed by the list of external organisations identified on the NICE final scope document for the technology. The websites searched, and the website URLs, are listed in Table A3.

The website searches were conducted on the 06/04/18.

The following search methods were used for each website:

1. For each website, if site-wide search functionality was available, separate searches were conducted using the following terms:

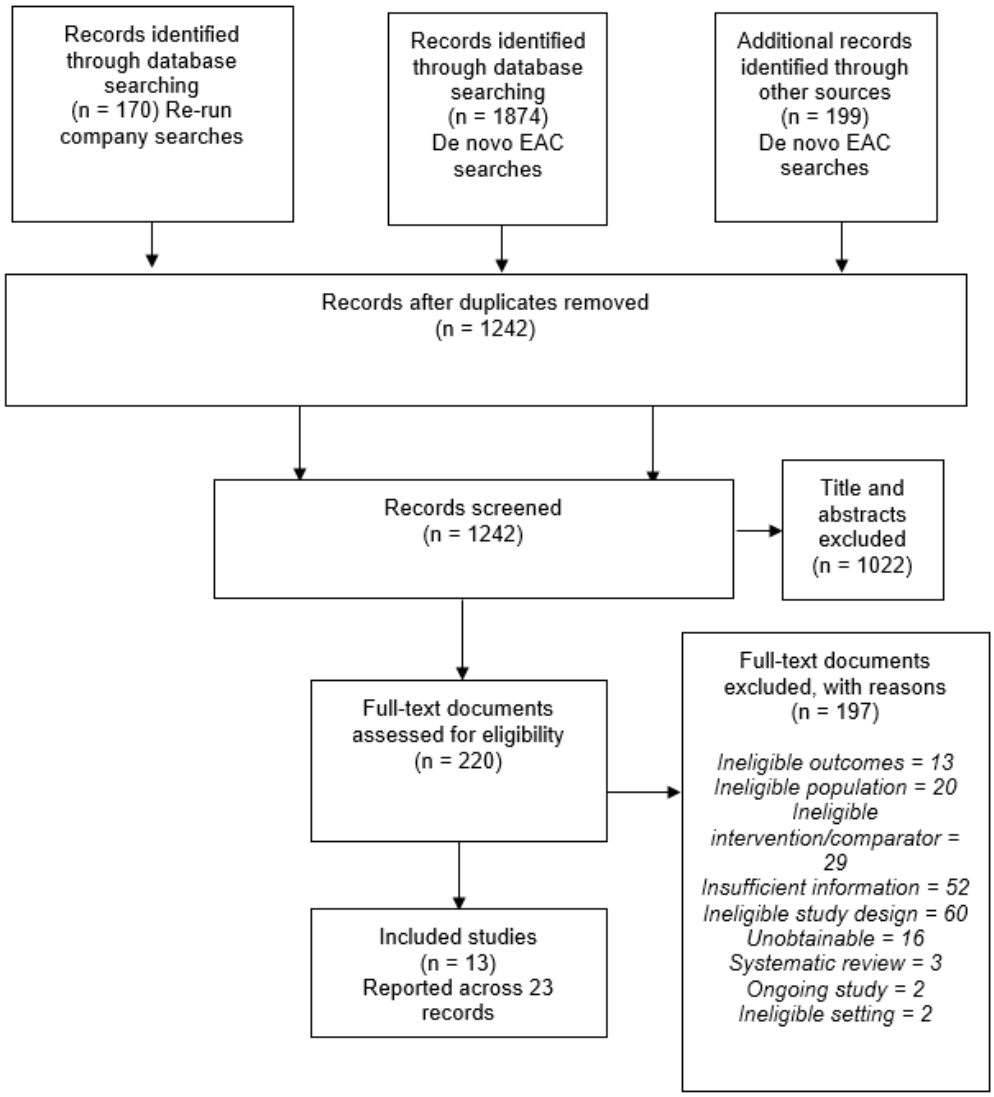
mepilex
mepilexR
mepilexTM

2. For each website, the following separate site-limited Google searches were conducted:
site:[website URL] mepilex
site:[website URL] mepilexR
site:[website URL] mepilexTM

Returned results were assessed by the searcher for potential relevance. Results judged to be potentially relevant were retrieved for further assessment.

The number of results retrieved for each website search is shown in Table A4.

PRISMA flow diagram showing studies assessed from the re-run company's clinical evidence searches and the EAC *de novo* searches – Clinical review



*records deduped against original and new search.

Appendix B: Exclusion reasons by the EAC based on reassessment of the included studies using the company's selection criteria

Included study by the company	Exclusion reason based on the EAC's reassessment of the study using the company's selection criteria
Baker 2014 (Baker 2014)	The EAC would have excluded this study as there are insufficient details reported concerning the stage or category of pressure ulcers (as defined by NPUAP et al. 2014 or an equivalent validated scale) amongst patients.
Cornish 2017 (Cornish 2017)	This was included by the company as an eligible systematic review. However, the EAC does not consider this review 'systematic' based on the methodology reported in the paper. The EAC would have excluded this study due to an ineligible study design.
Haisley 2015 (Haisley et al. 2015)	The EAC would have excluded this study as there are insufficient details reported concerning the stage or category of pressure ulcers (as defined by NPUAP et al. 2014 or an equivalent validated scale) amongst patients. Further, there are insufficient details reported about the intervention (i.e. nowhere in the publication does it explicitly state that Mepilex Border dressings were used).
Huang 2015 (Huang et al. 2015)	The EAC would have excluded this meta-analysis because there are insufficient details reported about the interventions that were evaluated in the included studies. The interventions are referred to as simply "foam dressings". No further details on the type of foam dressing are reported.
Koerner 2011 (Koerner 2011)	The EAC would have excluded this study as there are insufficient details reported about the population. The results reported by the authors suggest that the study population included patients with different stages/categories of pressure ulcer. Results were not reported separately for patients per pressure ulcer stage. Further, there are limited details reported about the intervention (i.e. nowhere does it explicitly state that Mepilex dressings were used).
Lientz 2013 (Lientz 2013)	The EAC would have excluded this study as there are insufficient details reported concerning the stage or category of pressure ulcers (as defined by NPUAP et al. 2014 or an equivalent validated scale) amongst patients.
Muldoon 2010 (Muldoon et al. 2010)	The authors reported that patients received an initial skin assessment on admission. However, it is not clearly stated whether or not patients had previous pressure damage before being admitted. Therefore, the EAC would have excluded this study based on insufficient information.
NPUAP 2014 (National Pressure Ulcer Advisory Panel 2014a)	This was included by the company as an eligible systematic review. However, the EAC does not consider this review 'systematic' based on the methodology reported in the paper. The EAC would have excluded this study due to an ineligible study design.
Padula 2017 (Padula 2017)	This study was included by the company as an observational comparative study. However, this paper reports a budget impact analysis, which was based on an observational study. The EAC would have excluded this study from the clinical review due to an ineligible study design.
Qiuli and Qiongyu 2010 (Bao and Ji 2010)	The EAC would have excluded this study due to an ineligible population. The results are reported for a mixed population, which comprises of patients with and without previous pressure ulcers. Results are not reported separately for the proportion of patients that do meet the company's eligibility criteria.
Sullivan 2015 (Sullivan 2015)	The EAC would have excluded this study due to an ineligible (mixed) population. Whilst the authors do report results separately for the intervention of interest (i.e. Mepilex Border/Heel) they are not

Included study by the company	Exclusion reason based on the EAC's reassessment of the study using the company's selection criteria
	reported separately for the specific population of interest (i.e. <= category 1 pressure ulcers).

Appendix C: List of excluded studies by the EAC

Study	Reason for exclusion
A Longitudinal Study to Evaluate an Extracellular Matrix (MatriStem®) for the Treatment of Diabetic Foot Ulcers. Identifier: NCT02750280. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://clinicaltrials.gov/show/NCT02750280.	Ineligible patient population
A RCT to Compare Performance of Two Foam Dressings on Patient Well-being Related Endpoints. Identifier: NCT02053337. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2014. Available from https://ClinicalTrials.gov/show/NCT02053337.	Ineligible patient population
Alvarez Vázquez JC, Estany Gestal A, Álvarez Suárez T, Mosquera JB, Castro Prado J, Gutiérrez Moeda E, et al. Prevention of deterioration of the cutaneous integrity in the sacral area through the application of an atraumatic self-adherent foam dressing. Metas de Enfermería. 2014;17(2):14-20.	Unobtainable
Anonymous. Spot Light. JCN. 2007;21(7):10.	Unobtainable
Atkin L, Stephenson J, Bateman SD. Foam dressings: A review of the literature and evaluation of fluid-handling capacity of four leading foam dressings. Wounds UK. 2015;11(1):75-81.	Ineligible study design
Atkinson RA, Cullum NA. Interventions for pressure ulcers: A summary of evidence for prevention and treatment. Spinal Cord. 2018;56(3):186-98.	Ineligible study design
Augusto FS, Blanes L, Zao PP, Ferreira LM. Hydrocellular foam dressing in prevention of pressure ulcers in critical patient-case report. Wound Repair Regen. 2015;23(2):A15-A15.	Insufficient information
Baker G. Nursing driving excellence: Preventing pressure ulcers in the high-risk population (poster presentation). In: Symposium on Advance Wound Care Fall, Las Vegas, Nevada, United States of America; 2014.	Ineligible outcomes
Baldwin C. Mepilex border sacrum used prophylactically to prevent sacrum pressure ulcers: A quality improvement project. Walden University; 2014.	Ineligible study design
Bao Q, Ji Q. Observation on effect of Mepilex on the prevention and treatment of pressure sores. Chin J Med Nurs. 2010:	Ineligible patient population
Bateman SD, Roberts S. Moisture lesions and associated pressure ulcers: Getting the dressing regimen right. Wounds UK. 2013;9(2):97-102.	Insufficient information
Beeckman D, Schoonhoven L, Kottner J, Moore Z, Meaume S, Fletcher J. Meeting report: Pressure ulcer prevention and management: do we all agree? Wounds Int. 2017;8(3):40-45.	Ineligible study design
Bell-Syer SEM. Review: Little evidence exists for type of dressing or support surface or for nutritional supplements for pressure ulcers. Evid Based Nurs. 2009;12(4):118-18.	Ineligible study design
Berbecar-Zeca EC, Stanciulescu EL, Chiotoroiu A, Grintescu IM. Pressure ulcer in the ICU and the use of biomaterials. Industria Textila. 2016;67(6):375-79.	Ineligible study design
Beth Smith ME, Totten A, Hickam DH, Fu R, Wasson N, Rahman B, et al. Pressure ulcer treatment strategies: A systematic comparative effectiveness review. Ann Intern Med. 2013;159(1):39-50.	Ineligible comparator
Bhattacharya S, Mishra RK. Pressure ulcers: Current understanding and newer modalities of treatment. Indian Journal of Plastic Surgery. 2015;48(1):4-16.	Unobtainable
Black J, Alves P, Brindle CT, Dealey C, Santamaria N, Call E, et al. Use of wound dressings to enhance prevention of pressure ulcers caused by medical devices. Int Wound J. 2015;12(3):322-27.	Ineligible study design
Black J, Clark M, Dealey C, Brindle CT, Alves P, Santamaria N, et al. Dressings as an adjunct to pressure ulcer prevention: Consensus panel recommendations. Int Wound J.12(4):484-88.	Ineligible study design
Black J. Evidence-based pressure ulcer prevention: Setting the standard. In: 19th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel; 21st September 2017: Belfast, Northern Ireland. Available from:	Ineligible study design

Study	Reason for exclusion
http://epuap2017.org/fileadmin/user_upload/EPUAP/Katalog_EPUAP_2017_FINAL.pdf	
Black J. Pressure ulcer prevention and management: A dire need for good science. Ann Intern Med. 2015;162(5):387-88.	Ineligible study design
Black J. Preventing heel pressure ulcers. Nursing. 2004;34(11):17.	Ineligible study design
Blaschak P, Thuet R. Implementation of a comprehensive pressure injury prevention program in a 400-bed acute care academic hospital in the Southwestern United States. In: Journal of Wound Ostomy & Continence Nursing/WOCN Society's 49th Annual Conference, Salt Lake City, Utah; May 19th-23rd. 2017. S53-S53	Insufficient information
Bluestein D, Javaheri A. Pressure ulcers: Prevention, evaluation, and management. Am Fam Physician. 2008;78(10):1186-94.	Ineligible study design
Bolton L. Evidence corner. Wounds. 2016;28(10):376-78.	Ineligible study design
Bouza C, Saz Z, Munoz A. Efficacy of advanced dressings in the treatment of pressure ulcers: A systematic review. J Wound Care. 2005;14(5):193-99.	Ineligible patient population
Brett DW. Impact on pain control, epidermal stripping, leakage of wound fluid, ease of use, pressure reduction, and cost-effectiveness. Home Healthc Nurse. 2006;24(10S):S15-9.	Ineligible study design
Brindle CT. Identifying high-risk ICU patients: Use of an absorbent soft silicone self-adherent bordered foam dressing to decrease pressure ulcers in the surgical trauma ICU patient. J Wound Ostomy Continence Nurs. 2009;36(3):S27-S27.	Insufficient information
Brindle CT. Outliers to the Braden Scale: Identifying high-risk ICU patients and the results of prophylactic dressing use. WCET Journal. 2010;30(1):11-18.	Ineligible outcomes
Britt C, Arwood L, Wilkinson L, Penoyer D, Sole M. Impact of implementing a critical care specific pressure ulcer prevention bundle: A pilot study. Crit Care Med. 2015;43(12):215-16.	Insufficient information
Brown J. The role of dressings in the prevention of pressure ulcers. Br J Nurs. 2016;25(15 Suppl):S6-S12.	Ineligible study design
Brown-Etris M, Milne CT. Use of a foam dressing with a unique spokeshaped delivery system* on pressure ulcers of the heel and elbow. J Wound Ostomy Continence Nurs. 2007;34(3):S30-S31.	Ineligible intervention
Butcher M, Thompson G. Dressings can prevent pressure ulcers: Fact or fallacy? The problem of pressure ulcer prevention. Wounds UK. 2009;5(4):80-93.	Ineligible study design
Canadian Agency for Drugs and Technologies in Health. Polyurethane foam dressings for the prevention of pressure ulcers: A review. Review. Ottowa: Canadian Agency for Drugs and Technologies in Health; 2011.	Ineligible study design
Cannon BC, Cannon JP. Management of pressure ulcers. Am J Health Syst Pharm. 2004;61(18):1895-907.	Ineligible study design
Cano A, Smits D, Corvino P. Efficacy of the prohylactic use of silicone foam dressing for the prevention of pressure ulcers in patients: An observational study in a 24 bed cardiovascular and cardiac intensive care unit. J Wound Ostomy Continence Nurs. 2011;38(3):S73-S73.	Insufficient information
Chadwick P, Haycocks S. Mepilex® Border Heel and the treatment of foot ulcers: A case series. Diabet Foot J. 2016;19(2):102-09.	Ineligible patient population
Chaiken N. Reduction of hospital acquired pressure ulcers in the intensive care unit. J Wound Ostomy Continence Nurs. 2011;38:S8-S8.	Insufficient information
Chan M. Pressure ulcer prevention: Use of prophylactic multilayer adhesive foam dressings in intensive care unit. J Wound Ostomy Continence Nurs. 2014;41:S67-S67.	Insufficient information

Study	Reason for exclusion
Chou R, Dana T, Bougatsos C, Blazina I, Starmer A, Reitel K, et al. Pressure ulcer risk assessment and prevention: Comparative effectiveness. Review. Rockville, MD: Agency for Healthcare Research and Quality; 2013.	SR for checking
Clark M, Black J, Alves P, Brindle CT, Call E, Dealey C, et al. Systematic review of the use of prophylactic dressings in the prevention of pressure ulcers. Int Wound J. 2014;11(5):460-71.	Ineligible study design
Clinical Investigation of Two Different Wound Dressings. Identifier: NCT02904200. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://clinicaltrials.gov/show/NCT02904200.	Ineligible intervention
Coggins T. Using a hydrocellular foam dressing with silicone adhesive as part of a comprehensive pressure ulcer prevention plan: results from five us hospital ICUs. J Wound Ostomy Continence Nurs. 2012;39(3):S61-S61.	Insufficient information
Connection found between dressing and decreased pressure injury. Ostomy Wound Manage. 2017;63(9):46-46.	Ineligible study design
Cooper M, Godke J, Nasca J. Building for change: Implementing pressure injury prevention. In: WOCN 49th Annual Conference 2017: Salt Lake City, Utah; CS15. Available from: http://wocnconference.com/wocn2017/Public/Enter.aspx	Insufficient information
Cooper M, Godke J, Nasca J. Bundling for change: Implementing pressure injury preventione. In: Journal of Wound Ostomy & Continence Nursing/WOCN Society's 49th Annual Conferenc, Salt Lake City, Utah; May 19-23. 2017. S13-S13	Insufficient information
Cornish L. The use of prophylactic dressings in the prevention of pressure ulcers: A literature review. Br J Community Nurs. 2017;22(Suppl 6):S26-S32.	Ineligible study design
Cubit K, McNally B, Green P. Get behind it! Taking the pressure off in the Emergency Department. In: Australasian Emergency Nursing Journal/8th International Conference for Emergency Nurses, The National Convention Centre, Canberra; 14-16 October. 2010. 136-36	Insufficient information
Cullum N, Petherick E. Pressure ulcers. BMJ Clin Evid. 2008;03:1901.	Ineligible study design
Culver E, Pezzella P, Langin J, Abbott L, Phearman L. Preventing hospital-acquired heel pressure injuries from taking root. In: Journal of Wound Ostomy & Continence Nursing/WOCN Society's 49th Annual Conference, Salt Lake City, Utah; May 19-23. 2017. S38-S38	Insufficient information
Culver E, Pezzella P, Langin J, Abbott L, Phearman L. Preventing hospital-acquired heel pressure injuries from taking root. In: WOCN 49th Annual Conference 2017: Salt Lake City, Utah; PI34. Available from: http://wocnconference.com/wocn2017/Public/Enter.aspx	Insufficient information
Daukste M. Mepilex border sacrum dressing use for pressure ulcers prevention in period of open heart surgery and ICU. Cardiol. 2013;1:33.	Ineligible outcomes
Davies P, McCarty S, Hamberg K. Silver-containing foam dressings with Safetac: a review of the scientific and clinical data. J Wound Care. 2017;26(Suppl 6a):S1-S32.	Ineligible intervention
Davies P, Rippon M. Evidence review: The clinical benefits of Safetac technology in wound care. J Wound Care. 2008;Suppl:3-31.	Ineligible study design
Davies P, Rippon M. Evidence review: The clinical benefits of Safetac® technology in wound care. Ostomy Wound Manage. 2008:4-31.	Ineligible study design
Davies P. Role of multi-layer foam dressings with Safetac in the prevention of pressure ulcers: A review of the clinical and scientific data. J Wound Care. 2016;25(1 Suppl):S1, S4-23.	Unobtainable
Dealey C, Posnett J, Walker A. The cost of pressure ulcers in the United Kingdom. J Wound Care. 2012;21(6):261-66.	Ineligible study design
Dealey C. Review: Evidence of the effectiveness of hydrocolloids for healing pressure ulcers is limited. Evid Based Nurs. 2008;11(4):115-15.	Ineligible study design

Study	Reason for exclusion
Delozier J, Freese C, McLaughlin K, Eleftherakis E. Prevention of device-related pressure ulcers in ICU: An interdisciplinary approach. In: WOCN 48th Annual Conference 2016: Montreal, Canada; PI16-019.	Ineligible patient population
Donovan R, Schindler P. Dollars, collaboration, and pressure ulcer pressure (PUP): Saving upwards of a million by achieving zero. In: WOCN 48th Annual Conference 2016: Montreal, Canada; PI16-076.	Insufficient information
Doughty D. Studies on the use of silicone foam dressing for prevention of sacrococcygeal breakdown in high-risk patients. J Wound Ostomy Continence Nurs. 2012;39(2):150-1.	Ineligible study design
Edwards J. Mepilex Border: A product comparison. JCN. 2003;17(9):46-47.	Ineligible study design
Edwards MB, Lynch JH. Head over heels for prevention: Use of a silicone bordered foam heel dressing in the prevention of pressure ulcers (poster presentation). In: Symposium on Advanced Wound Care Fall, Las Vegas, Nevada, United States of America; 2014.	Ineligible outcomes
Effect of soft silicone foam dressing compared to film transparent dressing in Pressure Ulcer prevention. Identifier: RBR-4s8qjx. In: Brazilian Clinical Trials Registry [internet]. Rio De Janeiro: Instituto de Informação Científica e Tecnológica em Saúde: 2017. Available from http://www.ensaiosclinicos.gov.br/rg/RBR-4s8qjx/.	Ineligible intervention
Effectiveness of Two Silicone Dressings for Sacral and Heel Pressure Ulcer Prevention. Identifier: NCT02295735. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2015. Available from https://ClinicalTrials.gov/show/NCT02295735.	Ineligible outcomes
Ekström A. Can a dressing prevent pressure ulcers in orthopedic care? In: 18th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2015: Ghent, Belgium; P33. Available from: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf	Insufficient information
Evans J. Care study: Managing heel ulcers in individuals with diabetes and extensive peripheral vascular disease. J Tissue Viability. 2009;18(4):129-30.	insufficient information
Ferrer Sola M, Espaulella Panicot J, Altimires Roset J, Ylla-Catala Bore E, Moreno Susi M. Comparison of efficacy of heel ulcer prevention between classic padded bandage and polyurethane heel in a medium-stay hospital: Randomized controlled trial. Rev Esp Geriatr Gerontol. 2013;48(1):3-8.	Ineligible intervention
Feuchtinger J. Preventing decubitus ulcer in heart surgery interventions: Visco-elastic foam layer on the operating room table - a study. Pflege Z. 2006;59(8):498-501.	Ineligible patient population
Fletcher J. Pressure ulcer prevention pathway symposium: A focus on heels. In: 18th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2015: Ghent, Belgium. Available from: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf	Unobtainable
Forni C, Loro L, Tremosini M. Use of polyurethane foam inside plaster casts to prevent the onset of heel sores in the population at risk: A controlled clinical study. J Clin Nurs. 2011;20(5-6):675-80.	Ineligible intervention
Forni C. Effectiveness of using a new polyurethane foam multi-layer dressing in the sacral area to prevent the onset of pressure ulcer in the elderly with hip fractures. Randomized controlled trial. In: SAWC; April 25th - 29th 2018: Charlotte, NC; CR-010. Available from: http://www.sawc.net/spring/sites/default/files/Accepted%20SAWC%20Spring%202018%20Abstracts%20-%20Poster%20Abstract%20Web%20Lisitingv%203.22.2018%20-%20With%20Numbers.pdf	Unobtainable
Garcia-Molina P, Balaguer-Lopez E, Quesada-Ramos C. Searching solutions for avoiding and diminishing the effect of local pressure in children. Ostomy Wound Manage. 2012;58(1):1.	Unobtainable
Gentry T, Wright A. The 'sacral heart' dressing study: Use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings (poster	Insufficient information

Study	Reason for exclusion
presentation). In: The Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America; 2010.	
Goossens A, Polfliet M, Paquay L. The role of materials and technical aids in pressure ulcer prevention. Ned Tijdschr Geneeskd. 2007;63(23):1166-68.	Ineligible study design
Gordon J, Stankiewicz M, Pollock H, Christensen M, Barker-Gregory N, Dulhunty J. A trial of two prophylactic sacral dressings (2PSD) in the prevention of Stage 1 sacral pressure injury in the critically ill patient: A study protocol. Wound Pract Res. 2017;25(2):82-86.	Ongoing trial/study
Grey JE, Enoch S, Harding KG. Pressure ulcers. BMJ. 2006;332:472-75.	Ineligible study design
Haesler E. Evidence summary: Pressure injuries: Preventing medical device related pressure injuries. Wound Pract Res. 2017;25(4):214-16.	Ineligible study design
Haggard C, Hodgin S, Lupear B, Weaver S, Mathews M. Preventing pressure injuries in the prone perioperative patient. In: WOCN 50th Annual Conference 2018: Philidelphia, PA; CS09. Available from: https://wocn.confex.com/wocn/2018am/webprogram/start.html	Insufficient information
Haisley V, Potter K, Wallace J, George R, Betsill K. An ounce of prevention: The use of a soft silicone five-layer bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting. J Wound Ostomy Continence Nurs. 2015;42(3):S48-S49.	Insufficient information
Haisley V, Potter K, Wallace J, George R, Betsill K. An ounce of prevention: The use of a soft silicone five-layer bordered foam heel dressing to decrease the incidence of hospital-acquired heel pressure ulcers in an acute care setting. J Wound Ostomy Continence Nurs. 2015;42(3):S48-S49.	Insufficient information
Harding K, Gray D, Timmons J, Hurd T. Evolution or revolution? Adapting to complexity in wound management. Int Wound J. 2007;4(Suppl 2):1-12.	Ineligible study design
Hardy M. "Happy Hiney Program" or how we reduced our hospital-acquired pressure injuries by over 80% on our magnet journey. In: WOCN Society's 49th Annual Conference, Salt Lake City, Utah; May 19-23. 2017. S33-S33	Insufficient information
Hardy M. "Happy Hiney Program" or how we reduced our hospital-acquired pressure injuries by over 80% on our magnet journey. In: WOCN 49th Annual Conference 2017: Salt Lake City, Utah; PI20. Available from: http://wocnconference.com/wocn2017/Public/Enter.aspx	Insufficient information
Hardy M. Reducing HAC pressure ulcers with foam silicone dressings. J Wound Ostomy Continence Nurs. 2012;39(3):S54-S54.	Insufficient information
Hargasova M, Kovacikova L. Prevention of sacral pressure ulcers in pediatric cardiac intensive care unit. In: 18th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2015: Ghent, Belgium; 24. Available from: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf	Insufficient information
Hayes C, Gillespie B, Carano A, Morris C. Expansion of PUPP bundle required to sustain pressure ulcer reduction across acute care units. In: WOCN 47th Annual Conference 2015: San Antonio, Texas; PR15-067. Available from: http://www.wocnconference.com/wocn2015/Public/Enter.aspx	Insufficient information
HAYES Inc. Oasis wound matrix (Cook Biotech Inc.) for lower extremity ulcers (Healthcare technology brief publication). Lansdale: HAYES Inc; 2010..	Ineligible patient population
Health Quality O. Management of chronic pressure ulcers: An evidence-based analysis. Ont Health Technol Assess Ser. 2009;9(3):1-203.	Ineligible patient population
Holte HH, Underland V, Hafstad E. Systematic reviews on preventing pressure ulcers: A systematic review. Review: National Institute of Public Health - Division of Health Services; 2016. 2016-11.	Ineligible study design
Huang L, Woo KY, Liu LB, Wen RJ, Hu AL, Shi CG. Dressings for preventing pressure ulcers: A meta-analysis. Adv Skin Wound Care. 2015;28(6):267-73.	Ineligible intervention

Study	Reason for exclusion
Hunt DL. Diabetes: Foot ulcers and amputations. Clin Evid (Online). 2011;26:26.	Ineligible patient population
Jiménez García JF, Abad García MM. Effectiveness of Mepilex® Border and Mepilex® Border Lite dressings in wound care. Metas de Enfermería. 2010;13(5):54-59.	Ineligible study design
Jin J, Fu X. Nursing care of pressure sore patients treated with sungran combined with Mepilex. Chin Nurs Res. 2016;30(1C):351-53.	Ineligible intervention
Johnstone A, McGown K. Innovations in the reduction of pressure ulceration and pain in critical care. Wounds UK. 2013;9(3):80-84.	Ineligible study design
Juele-Schuster J. The 6 mile journey.....Protecting the skin of 228 patients and residents during relocation to a new facility. In: WOCN 47th Annual Conference 2015: San Antonio, Texas; PR15-029. Available from: http://www.wocnconference.com/wocn2015/Public/Enter.aspx	Insufficient information
Kattell D, Whitmore L. Case Study 7: When a foam is not enough in managing sacral pressure ulcers. Br J Nurs. 2013:P18-P18.	Ineligible intervention
Koerner S, Adams D. Does the use of an absorbent soft silicone self-adherent bordered foam improve quality of care by decreasing incidence of hospital acquired pressure ulcers? J Wound Ostomy Continence Nurs. 2011;38:S70-S70.	Insufficient information
Koerner S. Does the use of an absorbent soft silicone self-adherent bordered foam improve quality of care by decreasing incidence of hospital acquired pressure ulcers? In: Scientific and clinical abstracts from the 43rd Annual Wound, Ostomy and Continence Nurses Conference, New Orleans, Louisiana, New Orleans, Louisiana; June 4-8. 2011. 5315	Insufficient information
Kyuwon RN. Pressure ulcer in gastroenterology unit in an acute care facility in Korea. In: 18th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2015: Ghent, Belgium; P13. Available from: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf	Unobtainable
Levy A, Frank MB-O, Gefen A. The biomechanical efficacy of dressings in preventing heel ulcers. J Tissue Viability. 2015;24(1):1-11.	Ineligible study design
Lientz J. Dollars and sense: economic value in HAPU/sDTI prevention. In: Poster presentation at National Pressure Ulcer Advisory Panel Biennial Conference, Houston, Texas, United States of America, 2013.	Ineligible outcomes
Lisco C. Evaluation of a new silicone gel-adhesive hydrocellular foam dressing as part of a pressure ulcer-prevention plan for ICU patients. In: Journal of Wound Ostomy & Continence Nursing/Scientific and Clinical Abstracts from the WOCN Society's 45th Annual Conference; June 22-26 2013: Seattle, Washington: Lippincott Williams & Wilkins; S61-2.	Ineligible intervention
Mancini S. How silicone wound contact layers promote healing and patient comfort. JCN. 2015;29(5):57-62.	Ineligible study design
Mathias JM. Use of refined protocols reduces pressure ulcer rates. OR Manager. 2013;29(12):1-1.	Ineligible study design
McNutt-Clarke B. Use of a new silicone-gel adhesive hydrocellular foam dressing for pressure ulcer prevention and treatment. J Wound Ostomy Continence Nurs. 2013;40:S27-S27.	Insufficient information
Meuleneire F. A case study evaluation of Safetac dressings used for paediatric wounds. Wounds UK. 2009;5(2):12-18.	Ineligible patient population
Miguel L, Bou J, Soriano J. Economics of pressure-ulcer care: Review of the literature on modern versus traditional dressings. J Wound Care. 2007;16(1):5-9.	Ineligible intervention
Miller SK, Sharma N, Aberegg LC, Blasiole KN, Fulton JA. Analysis of the pressure distribution qualities of a silicone border foam dressing. J Wound Ostomy Continence Nurs. 2015;42(4):346-51.	Ineligible patient population

Study	Reason for exclusion
Milne C. After the fact: Use of a multilayered hydrocellular foam in the prevention of reinjuring recently resolved pressure ulcers. J Wound Ostomy Continence Nurs. 2016;43(3):S33-S33.	Insufficient information
Mölnlycke. UK NICE publishes Medtech Innovation Briefing on Mepilex® Border dressings for preventing pressure ulcers. (1747-728X). 2017.	Ineligible study design
Moore Zena EH, Webster J. Dressings and topical agents for preventing pressure ulcers. Cochrane Database Syst Rev. 2013; (8)	SR for checking
Morris C, Emsley P, Marland E, Meuleneire F, White R. Use of wound dressings with soft silicone adhesive technology. Paediatr Nurs. 2009;21(3):38-43.	Ineligible intervention
Muldoon C, Grossman N, Lawrence P. Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cariovascular ICU (poster presentation). In: The Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomol Therapists, Phoenix, Arizona, United States of America; 2010.	Ineligible outcomes
Nakagami G, Sanada H, Konya C, Kitagawa A, Tadaka E, Tabata K. Comparison of two pressure ulcer preventive dressings for reducing shear force on the heel. J Wound Ostomy Continence Nurs. 2006;33(3):267-72.	Ineligible outcomes
National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and treatment of pressure ulcers: Clinical practice guideline. Perth, Australia: Cambridge Media; 2014.	Ineligible study design
Nayak D, Srinivasan K, Jagdish S, Rattan R, Chatram VS. Bedsores: "Top to bottom" and "bottom to top". Indian J Surg. 2008;70(4):161-8.	Ineligible study design
Nicolas B, Moiziard AS, Barrois B, Colin D, Michel JM, Passadori Y, et al. Which medical device and/or which local treatment for prevention in patients with risk factors of pressure sores in 2012. Towards development of French guideline for clinical practice. Ann Phys Rehabil Med. 2012;55(7):482-88.	Ineligible intervention
Pabón-Carrasco M, Juárez-Jiménez JM, Reina-Bueno M, Coheña-Jiménez M. Behavior of provisional pressure-reducing materials in diabetic foot. J Tissue Viability. 2016;25(2):143-49.	Ineligible study design
Padula WV, Mishra MK, Makic MB, Sullivan PW. Improving the quality of pressure ulcer care with prevention: A cost-effectiveness analysis. Med Care. 2011;49(4):385-92.	Insufficient information
Padula WV. Effectiveness and value of prophylactic 5-layer foam sacral dressings to prevent hospital-acquired pressure injuries in acute care hospitals: An observational cohort study. J Wound Ostomy Continence Nurs. 2017;44(5):413-19.	Ineligible study design
Pastor Blasco P. Mepilex® Border Post-Op, de Mólnlycke Health Care, fue considerado Producto Sanitario del Año el pasado 2 de octubre en el Congreso ANECORM celebrado en Pamplona. Rev Enferm. 2015;38(11):74-75.	Ineligible intervention
Performance of Flexible Self-adherent Absorbent Dressing Coated With a Soft Silicone Layer After Hip -,Knee- Arthroplasty, Primary Spine Surgery in Comparison to a Standard Wound Dressing. Identifier: NCT02771015. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2014. Available from https://ClinicalTrials.gov/show/NCT02771015.	Ineligible patient population
Pezzella P, Phearman L, Smith A. Not leaving a mark. In: WOCN 47th Annual Conference 2015: San Antonio, Texas; PR15-051. Available from: http://www.wocnconference.com/wocn2015/Public/Enter.aspx	Insufficient information
Pham B, Stern A, Chen W, Sander B, John-Baptiste A, Thein HH, et al. Preventing pressure ulcers in long-term care: A cost-effectiveness analysis. Arch Intern Med. 2011;171(20):1839-47.	Ineligible intervention
Pham B1 TL, Mahoney J, Goodman L, Paulden M, Poss J, Li J, Ieraci L, Carcone S, Krahn M. Early prevention of pressure ulcers among elderly patients admitted through emergency departments: A cost-effectiveness analysis. Ann Emerg Med. . 2011;58(5):468-78.	Ineligible intervention

Study	Reason for exclusion
Philbin S. Incorporating the use of an adhesive sacral foam dressing with a sodium Carboxymethylcelllulose contact layer in a hospital's pressure ulcer prevention program. In: Journal of Wound Ostomy & Continence Nursing/Scientific and Clinical Abstracts from the WOCN Society's 45th Annual Conference, Seattle, Washington; June 22-26. 2013. S21-S21	Ineligible intervention
Piatkowski A, Ulrich D, Seidel S, Abel M, Pallua N, Andriessen A. Randomized controlled pilot comparing collagen and foam dressings in pressure ulcer patients evaluating their influence on healing time, angiogenesis and proinflammatory cells. In: 15th conference nationale des plaies ET cicatrisations prevention et traitement; Jan 16 - 18 2011: Paris: France; 79.	Unobtainable
Piatkowski De Grzymala A, Ulrich D, Seidel D, Abel M, Pallua N, Andriessen A. RCT comparing collagen and foam dressings in pressure ulcers evaluating their influence on healing time angiogenesis and pro-inflammatory cells. EWMA journal. 2011; (2 Suppl): 42.	Insufficient information
Poitras V, Frey N. Polyurethane Foam Dressi insufficient information ngs for the Prevention of Pressure Ulcers: Clinical and Cost-Effectiveness and Guidelines. Ottowa: Canadian Agency for Drugs and Technologies in Health. ; 2017.	SR for checking
Polyurethane Foam on the Heel for Prevention in Children. Identifier: NCT03039179. In: ClinicalTrial.gov [internet]. Bethesda: US National Library of Medicine: 2014. Available from https://ClinicalTrials.gov/show/NCT03039179.	Ineligible intervention
Polyurethane Foam on the Sacrum for Prevention. Identifier: NCT02692482. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://ClinicalTrials.gov/show/NCT02692482.	Ineligible intervention
Post Market Clinical Follow-up Study. Identifier: NCT01841567. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2013. Available from https://ClinicalTrials.gov/show/NCT01841567.	Ineligible intervention
Pott FS, Meier MJ, Stocco JG, Crozeta K, Ribas JD. The effectiveness of hydrocolloid dressings versus other dressings in the healing of pressure ulcers in adults and older adults: A systematic review and meta-analysis. Rev Latino-Am Enfermagem. 2014;22(3):511-20.	Ineligible intervention
Pressure Injury Prevention in the ICU With Multi-Layer Foam Dressings. Identifier: NCT02962882. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://ClinicalTrials.gov/show/NCT02962882.	Ineligible outcomes
Pressure Ulcer Prevention in Intensive Care Unit (ICU). Identifier: NCT01356459. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2011. Available from https://ClinicalTrials.gov/show/NCT01356459.	Ineligible outcomes
Prevention of Sacral Pressure Ulcers With Preventive Dressings. Identifier: NCT01640418. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2012. Available from https://ClinicalTrials.gov/show/NCT01640418.	Ineligible outcomes
Prophylactic Dressing to Minimise Sacral Pressure Injuries in High Risk Hospitalised Patients: A Pilot Study. Identifier: ACTRN12613001328763. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: 1. Prophylactic Dressing to Minimise Sacral Pressure Injuries in High Risk Hospitalised Patients: A Pilot Study. Identifier: ACTRN12613001328763. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2013. Available from http://www.anzctr.org.au/ACTRN12613001328763.aspx. National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2013. Available from http://www.anzctr.org.au/ACTRN12613001328763.aspx.	Ineligible outcomes
Ramundo J, Pike C, Pittman J. Do prophylactic foam dressings reduce heel pressure injuries? J Wound Ostomy Continence Nurs. 2018;45(1):75-82.	Unobtainable

Study	Reason for exclusion
Reddy M, Gill SS, Kalkar SR, Wu W, Anderson PJ, Rochon PA. Treatment of pressure ulcers: A systematic review. JAMA. 2008;300(22):2647-62.	Ineligible patient population
Reddy M. Pressure ulcers. Clin Evid (Online). 2011;05:1901.	Ineligible intervention
Righter B, Rodgers C, Rinauro M. Sacral breakdown prevention and continuous quality improvement. In: WOCN 47th Annual Conference 2015: San Antonio, Texas; PR15-007. Available from: http://www.wocnconference.com/wocn2015/Public/Enter.aspx	insufficient information
Saab IR, Solomon JF, Allen L, Siddiqui A. Hydrocellular foam dressing for preventing pressure ulcers: A randomized controlled trial. Wound Repair Regen. 2015;23(2):A37-A37.	insufficient information
Santamaria N, Gerdtz M, Kapp S, Wilson L, Gefen A. A randomised controlled trial of the clinical effectiveness of multi-layer silicone foam dressings for the prevention of pressure injuries in high-risk aged care residents: The Border III Trial. Int Wound J. 2018;(unpublished)	Ineligible setting
Santamaria N, Gerdtz M, Vassiliou T, Knott J, DeVincentis S, Sage S. The border trial: A prospective randomised controlled trial of the effectiveness of multi-layer silicone dressings in preventing intensive care unit pressure ulcers. EWMA journal. 2013; (1 Suppl): 93, abstract no.147.	Unobtainable
Santamaria N, Gerdtz MF, Vassiliou MT, Knott J. A prospective randomised controlled trial of the effectiveness of absorbent soft silicone self-adherent dressings in the prevention of sacral and heel pressure ulcers in critically ill ED/ICU patients. Acad Emerg Med. 2012;19(6):767.	Insufficient information
Santamaria N, Santamaria H. An estimate of the potential budget impact of using prophylactic dressings to prevent hospital-acquired PUs in Australia. J Wound Care. 2014;23(11):583-4, 86, 88-9.	Ineligible study design
Santamaria N. New clinical evidence-The clinical effectiveness of multi-layer silicone heel dressings. In: 18th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2015: Ghent, Belgium. Available from: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf	Unobtainable
Santamaria N. Preventing pressure ulcers in aged care: A randomised controlled trial of the effectiveness of prophylactic silicone foam dressings. In: 18th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2015: Ghent, Belgium. Available from: http://www.epuap.org/wp-content/uploads/2016/10/epuap-2015-abstract-book_web-small.pdf	Ineligible setting
Santamaria N. The clinical effectiveness of silicone dressings to prevent PU in aged care. In: 19th EPUAP Annual Meeting of the European Pressure Ulcer Advisory Panel 2017: Belfast, Northern Ireland. Available from: http://epuap2017.org/fileadmin/user_upload/EPUAP/Katalog_EPUAP_2017_FINAL.pdf	Ineligible study design
Scardillo J, Truland D, Riemenschneider K, Hazelton-Hardy K, Sheehan L, Boyle H, et al. Peri-operative pressure ulcer prevention initiative. In: WOCN 50th Annual Conference 2018: Philidelphia, PA; ePI101. Available from: https://wocn.confex.com/wocn/2018am/webprogram/start.html	Insufficient information
Shao M, Hussain Z, Thu HE, Khan S, de Matas M, Silkstone V, et al. Emerging trends in therapeutic algorithm of chronic wound healers: Recent advances in drug delivery systems, concepts-to-clinical application and future prospects. Crit Rev Ther Drug Carrier Syst. 2017;34(5):387-452.	Ineligible study design
Sibbald RG, Woo K, Price P, Harding K. An open randomised cross-over investigation assessing perceived pain at dressing change comparing soft silicone dressing with an adhesive hydrocellular polyurethane dressing in patients with chronic ulcer. In: 17th Conference of the European Wound Management Association, Glasgow, Scotland; 2-4 May. 2007. 198	Insufficient information
Silicone Adhesive Multilayer Foam Dressings to Prevent Pressure Ulcer. Identifier: NCT03442777. In: ClinicalTrials.gov [internet]. Bethesda: US	Ongoing trial/study

Study	Reason for exclusion
National Library of Medicine: 2018. Available from https://ClinicalTrials.gov/show/NCT03442777.	
Smith D. Use of a new foam wound dressing in 3 LTC patients with chronic pressure ulcers. J Wound Ostomy Continence Nurs. 2014;41:S38-S38.	Ineligible intervention
Smith IL, Brown S, McGinnis E, Briggs M, Coleman S, Dealey C, et al. Exploring the role of pain as an early predictor of category 2 pressure ulcers: A prospective cohort study. BMJ Open. 2017;7(1):e013623.	Ineligible intervention
Sopata M, Tomaszewska E, Machynska-Bucko Z, Kotlinska-Lemieszek A. Modern methods of conservative treatment of pressure ulcers. Postep Derm Alergol. 2012;29(1):40-46.	Ineligible study design
Sopata M. Pressure ulcers - prevention and conservative treatment. Fam Med Prim Care Rev. 2009;11(3):757-61.	Ineligible study design
Spencer A, Gazzani P, Thompson DA. Dressings: An emerging source of acrylate contact allergy. Br J Dermatol. 2016;175(Suppl 1):177.	Ineligible patient population
Stevens C. Moisture-control dressings in wound care. J Wound Ostomy Continence Nurs. 2006; 33(suppl 6S): S1-S19. J Wound Ostomy Continence Nurs. 2007;34(5):478-78.	Ineligible study design
Strauss R, Findley N, Preston A, Rao A. Prophylactic sacral foam dressing to prevent deep tissue injury in post-operative cardiac surgery patients. In: WOCN 50th Annual Conference 2018: Philidelphia, PA; R08. Available from: https://wocn.confex.com/wocn/2018am/webprogram/start.html	Insufficient information
Sullivan J, Martel T. Retrospective evaluation of a new silicone faced sacral foam dressing for pressure injury prevention. J Wound Ostomy Continence Nurs. 2017;44(3):S21-S22.	Insufficient information
Sullivan J, Martel T. Retrospective evaluation of a new silicone faced sacral-foam dressing for pressure injury prevention. In: WOCN 49th Annual Conference 2018: Salt Lake City, Utah; CS39. Available from: http://wocnconference.com/wocn2017/Public/Enter.aspx	Insufficient information
Sullivan R. Use of a soft silicone foam dressing to change the trajectory of destruction associated with suspected deep tissue pressure ulcers. Medsurg. 2015;24(4):237-42, 67.	Ineligible outcomes
Talosi G, Meszes A, Mader K, Csoma Z. Wound frequency and care in premature and full term neonates requiring intensive therapy. Journal of Perinatal Medicine/Conference: 11th World Congress of Perinatal Medicine. 2013;41(Suppl 1)	Ineligible patient population
Taradaj J. Prevention and treatment of pressure ulcers by newest recommendations from european pressure ulcer advisory panel (EPUAP): Practical reference guide for GPs. Fam Med Prim Care Rev. 2017;19(1):81-83.	Ineligible study design
Tayyib N, Coyer F. Effectiveness of pressure ulcer prevention strategies for adult patients in intensive care units: A systematic review. Worldviews Evid Based Nurs. 2016;13(6):432-44.	Ineligible study design
The effect of a silicone border foam dressing for prevention of pressure ulcers and incontinence-associated dermatitis in intensive care unit patients: Erratum.../Wound Ostomy Continence Nurs. 2014;41(5):424-429. J Wound Ostomy Continence Nurs. 2014;41(6):580-80.	Insufficient information
The Effect of Multilayer Silicone Foam compared to Transparent Film in Pressure Injury Prevention on Heels Due to the Surgical Position. Identifier: RBR-5gkng5. In: Brazilian Clinical Trials Registry [internet]. Rio De Janeiro: Instituto de Informação Científica e Tecnológica em Saúde: 2017. Available from http://www.ensaiosclinicos.gov.br/rg/RBR-5gkng5/.	Ineligible intervention
The Effect of Silicone Protective Pad on Pressure Ulcer. Identifier: IRCT2015110619919N3. In: Iranian Registry of Clinical Trials [internet]. Tehran: Ministry of Health and Medical Education (MOHME), Iran University of Medical Sciences (IUMS): 2016. Available from http://en.irct.ir/trial/17693.	Ineligible intervention
The effectiveness of soft silicone multi-layered foam dressings for preventing intraoperatively acquired pressure ulcers (IAPUS) in spinal surgery patients.	Ineligible intervention

Study	Reason for exclusion
Identifier: JPRN-UMIN000021696. In: UMIN Clinical Trials Registry [internet]. Tokyo: Korea Centers for Disease Control and Prevention (KCDC): 2016. Available from https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000025029.	
The Swedish Council on Health Technology A. Chronic ulcers in the elderly – prevention and treatment. Stockholm: The Swedish Council on Health Technology Assessment (SBU); 2014.	Unobtainable
Thomas DR. Prevention and treatment of pressure ulcers. J Am Med Dir Assoc. 2006;7(1):46-59.	Ineligible study design
Thomas DR. Prevention and treatment of pressure ulcers: What works? What doesn't? Cleve Clin J Med. 2001;68(8):704-7, 10-14, 17-22.	Ineligible study design
Thomas DR. The prevention and management of pressure ulcers. Rev Clin Gerontol. 2007;17(4):241-57.	Ineligible study design
Thul J, Valero E. Sacral pressure ulcer prevention in trauma patients. In: WOCN 47th Annual Conference 2015: San Antonio, Texas; RS15-024. Available from: http://www.wocnconference.com/wocn2015/Public/Enter.aspx	Insufficient information
Tickle J. Case Study 4: Pressure ulcer to sacrum. Br J Nurs. 2013:P11-P11.	Ineligible study design
Tobe-Sutton M. Sacral foam dressings for prevention in ICU patients. In: WOCN 50th Annual Conference 2018: Philadelphia, PA; PI25. Available from: https://wocn.confex.com/wocn/2018am/webprogram/start.html	Insufficient information
Tran JP, McLaughlin JM, Li RT, Phillips LG. Prevention of pressure ulcers in the acute care setting: New innovations and technologies. Plast Reconstr Surg. 2016;138(3 Suppl):232S-40S.	Ineligible study design
Truong B, Grigson E, Patel M, Liu X. Pressure ulcer prevention in the hospital setting using silicone foam dressings. Cureus. 2016;8(8):e730.	Ineligible study design
Tsao W-Y, Lo S-F, Harmod T, Lee R-P. A comparison of the efficacy of different wound dressing management techniques in preventing pressure ulcers. Hu Li Tsa Chih. 2013;60(4):65-75.	Unobtainable
Turbett K. Prophylactic dressings for pressure ulcer prevention in long-term care. In: WOCN 48th Annual Conference 2016: Montreal, Canada; PI46-048.	Ineligible study design
VanWyhe J, Willer S, Blackley M, Slevin A, Johnson P. Use of an absorbent soft silicone self-adherent bordered foam dressing to decrease incidence of sacral pressure ulcers in the ICU. J Wound Ostomy Continence Nurs. 2012;39(3):S68-S68.	Insufficient information
Viamontes L, Temple D, Wytall D, Walker A. An evaluation of an adhesive hydrocellular foam dressing and a self-adherent soft silicone foam dressing in a nursing home setting. Ostomy Wound Manage. 2003;49(8):48-52, 54-56, 58.	Ineligible patient population
Wagner D. Reducing pressure ulcers in the surgical cardiovascular patient population. In: WOCN 48th Annual Conference 2016: Montreal, Canada; PI16-026.	Insufficient information
Wagstaff MJD, Driver S, Coghlan P, Greenwood JE. A randomized, controlled trial of negative pressure wound therapy of pressure ulcers via a novel polyurethane foam. Wound Repair Regen. 2014;22(2):205-11.	Ineligible patient population
Walsh NS, Blanck A. Pressure ulcer prevention of sacral stage 2 and dti in critical care: A pilot study. J Wound Ostomy Continence Nurs. 2011;38(3):S31-S31.	Insufficient information
Walsh NS, Blanck AW, Smith L, Cross M, Andersson L, Polito C. Use of a sacral silicone border foam dressing as 1 component of a pressure ulcer prevention program in an intensive care unit setting. J Wound Ostomy Continence Nurs. 2012;39(2):146-9.	Insufficient information
Webb MK. Selection of soft silicone dressings to meet unique resident wound care needs in 1 county long-term care facility. In: Journal of Wound Ostomy & Continence Nursing/Scientific and clinical abstracts from the 40th Annual Wound, Ostomy and Continence Nurses Annual Conference, Baltimore, Maryland; 2008. S27-S29	Insufficient information

Study	Reason for exclusion
White R. A multinational survey of the assessment of pain when removing dressings. Wounds UK. 2008;4(1):14-22.	Ineligible patient population
Whitney R. Preventing pressure ulcers in the ICU: A performance improvement project. In: WOCN 49th Annual Conference 2017: Salt Lake City, Utah; PI25. Available from: http://wocnconference.com/wocn2017/Public/Enter.aspx	Insufficient information
Wiseman C. Wound management. Dissector. 2003;31(2):14-19.	Ineligible study design
Woo K. Using multi-layer foam dressing to prevent pressure injury in a long-term care setting. Surg Technol Int. 2018;31:12.	Unobtainable
Woo KY, Coutts PM, Price P, Harding K, Sibbald RG. A randomized crossover investigation of pain at dressing change comparing 2 foam dressings. Adv Skin Wound Care. 2009;22(7):304-10.	Ineligible patient population
Xiao Q, Yang Q, Lu H. Meta analysis of effect of foam dressing and hydrocolloid dressing on bedsore management. Chin Nurs Res. 2017;31(27):3397-400.	Ineligible study design
Zeek DM, Malandrino R, Perry R. The prophylactic use of a silicone border foam dressing for the prevention of sacral pressure ulcers in acute hip fracture patients requiring surgical repair. J Wound Ostomy Continence Nurs. 2014;41:S83-S83.	Insufficient information
강현욱, 고지운. 중환자실의 욕창 예방 중재 프로그램의 효과 : 메타 분석. J Korean Crit Care Nurs. 2018;11(1):67-78.	Unobtainable

Appendix D: Detailed critical appraisal of randomised controlled trials

Study name (acronym)	Was the method used to generate random allocations adequate?	Was the allocation of treatment adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were the care providers, participants and outcome assessors blind to treatment allocation?	Were there any unexpected imbalances in drop-outs between groups?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	EAC Comments
Aloweni 2017 (Aloweni et al. 2017)	**Yes** – Computer-generated table of simple random sampling (ratio 1:1:2)	**Yes** - Allocation list overseen by research coordinator who was not involved in the study. Opaque sealed envelopes used to maintain allocation concealment. Allocation assignment only made known to ward nurses after patients successfully enrolled	**Yes** – Groups were comparable on all major physiological and demographic characteristics on admission. No significant difference in terms of age, Braden score, nutrition status, skin colour, presence of heart disease or diabetes	**No** - Patients and care providers/data collectors (nurses) were not blinded due to the nature of the treatments	**Yes** - Dressing group: 29 drop-outs (3 sacral, 6 excoriation, 6 dying/death, 9 contamination of treatment, 5 requested withdrawal) Fatty acids oil group:18 drop-outs (6 sacral excoriation, 6 dying/death, 3 admission to ICU for critical illness, 2 contamination of treatment, 1 requested withdrawal) Standard care: 17 drop-outs (2 sacral excoriation, 1 diarrhoea, 1 operation >4 hr, 9 dying/death, 1 contamination of treatment, 3, requested withdrawal) No explanation of drop-outs or adjustments made	**No** – All outcomes measured appear to have been reported.	**Yes** (ITT analysis) No (Missing data) Intention-to-treat analysis was conducted but there were no details of how missing data were accounted for in the analysis. Per protocol baseline data and results were also reported	Power calculation reported. Authors reported that the study was slightly underpowered

Study name (acronym)	Was the method used to generate random allocations adequate?	Was the allocation of treatment adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were the care providers, participants and outcome assessors blind to treatment allocation?	Were there any unexpected imbalances in drop-outs between groups?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	EAC Comments
Kalowes 2016 (Kalowes et al. 2016)	**Yes** – Randomly permuted block design (2, 4, or 6 patients) with random patient order within a block. On ICU admission and after eligibility screening, participants randomized (1:1) by principal investigator or nurse by accessing the randomization programme	**Yes** – Group allocation was determined by accessing the randomization programme	**Yes** – The groups did not differ significantly in demographics and major physiological variables, including the APACHE III severity-of-illness score	**No** – Non-blinded. The authors highlighted that there was a risk of bias in reported findings but stated it was impossible to blind data collectors because of the nature of the intervention	**No** – There were 31 deaths in the intervention group and 36 in the control group, but not other drop-outs	**No** – All outcomes measured appear to have been reported.	**Yes** (ITT analysis) No (Missing data) The intention-to-treat analysis was appropriate. Patients who died during the study were accounted for, although the methods used were not described	Power calculation reported

Study name (acronym)	Was the method used to generate random allocations adequate?	Was the allocation of treatment adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were the care providers, participants and outcome assessors blind to treatment allocation?	Were there any unexpected imbalances in drop-outs between groups?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	EAC Comments
Santamaria 2015 (Santamaria et al. 2015) (BORDER)	**Yes** - Pre-prepared series of randomization envelopes, prepared using a computer-generated set of random numbers. Participants were randomized on admission to the ED and after eligibility screening by the ED nurse.	**Not clear** – Treatment allocation was conducted by the ED nurse following admission and eligibility screening, the pre-prepared assignment envelopes. It was not reported whether these envelopes were sealed, opaque or numbered	**Yes** – The groups were comparable on major physiological and demographic characteristics on admission to the ED	**No** – Open-label trial. The nature of the treatments made blinding impossible. All members of the research team underwent inter-rater reliability testing prior to data collection to ensure consistency in pressure ulcer identification and staging	**Not clear** – Intervention group: 17 lost to follow-up, 1 death in the ED and 38 discharged from ICU prior to first pressure ulcer assessment. Control group: 29 lost to follow-up, 3 deaths in the ED and 39 discharged from ICU prior to first pressure ulcer assessment. No adjustments made but some breakdown of losses to follow-up shown in the CONSORT flow chart	**Yes** – The cost-effectiveness of the dressings was reported in another publication.	**Not clear** – Reported to have used intention-to-treat analysis but the CONSORT flow diagram shows that the analysis data set excluded patients who died, were discharged before first assessment or were lost to follow-up. Methods used to account for missing data were not described	Power calculation reported

Study name (acronym)	Was the method used to generate random allocations adequate?	Was the allocation of treatment adequately concealed?	Were the groups similar at the outset of the study in terms of prognostic factors?	Were the care providers, participants and outcome assessors blind to treatment allocation?	Were there any unexpected imbalances in drop-outs between groups?	Is there any evidence to suggest that the authors measured more outcomes than they reported?	Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	EAC Comments
Walker 2017 (Walker et al. 2017)	**Yes** - Randomization (1:1 with random block sizes) through an online clinical trial coordinating website, which was accessed by the research nurse. Stratified approach used to ensure even distribution of participants diagnostic category (medical or surgical)	**Yes** - Protocol stated that stratified approach and 1:1 ratio with random block sizes ensured allocation concealment	**Unclear** - Groups appeared to be reasonably well matched (no formal analysis) and p-values presented for each factor. More females in routine care group (82% vs 59%; p=0.03). Also, more obese patients (67% vs 3%), but there were a lot of missing data	**Unclear** - Patients and healthcare professionals not blinded due to the nature of the treatments. Success of blinding of outcome assessor was dependent on level of atraumatic markings left on patient's skin by the dressing	**Unclear** - 3 patients excluded after randomization in the control group (2 protocol violations and 1 consent withdrawal) 5 patients in each group did not have their outcome assessed; reasons for this given overall not by group	**No** - No additional outcomes listed in protocol	**Yes** (ITT analysis) No (Missing data) Intention-to-treat analysis was conducted. The authors did not address the handling of missing data.	Power calculation not reported, although the authors considered the sample size was sufficient for a feasibility study Small sample size

Abbreviations: ED, emergency department; ICU, intensive care unit; ITT, intention-to-treat.

Appendix E: Detailed critical appraisal of comparative observational studies (CASP)

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Brindle 2012 Brindle et al. 2012)	**Yes** – Patients admitted to the cardiac surgery ICU were screened according to the inclusion and exclusion criteria. Group assignment (non-random) was based on predesignated rooms and room availability on call from the operating room. Charge nurse and ward personnel were unaware of the room designation and the patient's group assignment.	**Not clear** – Dressing application was depicted and described, and all staff were educated on how to apply the dressing. All patients received the dressing whilst in the operating room, and the same pre-/post-operative standard care, but patients who developed a pressure ulcer were given an individualized treatment plan.	**Not clear** – Outcome measures defined. Patients in both groups had daily skin assessments until discharge, but no clear definitions of stages or established classification systems were used for assessment. Blinding not possible due to the nature of the treatments.	**Yes** – 21 covariate factors, including confounding factors, were identified.	**Yes** - Covariate factors were compared between groups using appropriate statistical tests and an adjusted Cox proportional hazards model.	**No** – 5 patients without data collection forms; assignment group was not known. 6/56 patients in the intervention group and 4/39 in the control group did not complete the study.	**Not clear** - p-values and some confidence intervals presented, but no standard deviations	Small sample size Power of study reduced due to change in study design (and withdrawal of 2/3 study sites) All patients initially received the intervention in the operating room.

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Chaiken 2012 (Chaiken et al. 2012)	**Not clear** - Minimal inclusion/exclusion criteria applied to patients admitted to ICU. Control (retrospective) and intervention (prospective) patients were recruited over different time (35-month baseline period for control group followed by 6-month period for intervention group).	**Not clear** – Insufficient details of initial dressing application. Unclear if patients in both groups received same level of standard care, aside from mattress use. Staff had received training on use and application of dressing, and education on preventive interventions and skin assessments. WOC nurse assessed adherence to dressing application protocol on a daily basis	**No** – Outcome measure defined, but outcome assessment not the same in both groups. Prospective observation of intervention through daily skin assessments over 6 months (scale not reported). Retrospective data for control group from monthly skin assessments over 35-month period based on NDNQI procedure and verified by a WOC nurse.	**Not clear** - Insufficient details of patient demographics and clinical characteristics. Diagnoses and length of ICU stay were reported to be comparable between groups. Preventive measures were also discussed.	**Not clear** – Patient differences between the 2 groups were not considered. Both groups used similar prevention practices, with the exception that education and daily ICU visits by WOC nurses were only introduced for the intervention group.	**Not clear** – Limited follow-up details. Only reported that 4 of 5 patients with sacral pressure ulcers in the intervention group died.	**Not clear** – Results between groups could not be compared directly using inferential statistics since they used different outcome measures (prevalence and incidence).	Prospective intervention with retrospective control Power calculation not reported

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Cubit 2013 (Cubit et al. 2013)	**Not clear** – Defined inclusion and exclusion criteria applied to patients admitted to the ward via the emergency department. Unclear why participants invited to take part in the study comprised the intervention group whilst patients who weren't invited formed the control group.	**Not clear** – Insufficient details of initial dressing application. Unclear if patients in both groups received same level of treatment and standard care (intervention group had received prevention plan and control group had documented management plan). Staff had been educated to familiarise themselves with the product, risk assessment, prevention and treatment strategies. Unclear whether dressing application had been covered.	**No** – Outcome measure defined, but assessment not the same in both groups. Prospective observation of intervention group through 8-hourly skin assessments for duration of stay or end of trial. Pressure injuries graded using 4-stage system (AWMA approved). Retrospective audit of medical records for control group, with presence of pressure injuries validated using data from the hospital's incident reporting system.	**Not clear** - Limited patient characteristics (age, gender, LOS and reason for admission) provided. Standard care was not well defined: prevention plan recorded for intervention group patients and management plan for control group patients.	**No** - Authors stated that further research is needed to explore associations of other factors including nutrition, continence, mobility and comorbidities.	**Not clear** – Insufficient details of follow-up.	**Not clear** – p-value reported but no confidence interval.	Prospective intervention with retrospective data collection for control Small sample size Power calculation not reported. Mölnlycke Health Care provided the dressings and financial support for conferences.

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Jin 2018, unpublished	**Not clear** - Prospective intervention and retrospective control groups comprising patients receiving pressure prevention strategies prior to cardiac surgery at same hospital. Inclusion and exclusion criteria were clear for the prospective intervention group, but it was unclear whether the same criteria had been applied to patients in the control group.	**Not clear** – Insufficient details of standard prevention strategies, how the dressings were applied or by whom, in either intervention or control group.	**No** – Outcome measure defined, but assessment not the same in both groups. Prospective observation of intervention group based on skin assessments before and after surgery by experienced perioperative nurses. NUAP 2014 used to grade pressure ulcers. Retrospective data from medical charts of control group. Unclear whether same assessment procedures applied in both groups.	**Not clear** - Patient demographics, clinical characteristics, (including comorbid disease), and pre-existing risk factors for pressure ulcer formation were considered. Standard prevention care was not defined for either group.	**Yes** – Statistical comparison of patient demographics and clinical characteristics (particularly comorbid disease), and pre-existing risk factors for pressure ulcer formation.	**Yes** - All patients included in final analysis; no patients lost to follow-up.	**Not clear** - p-values reported but no confidence intervals.	Prospective study with retrospective control conducted over different time periods. Power calculation reported

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Haisley 2015 (Haisley et al. 2015)	**Not clear** – Clear inclusion/exclusion criteria for patients admitted to the coronary care unit and cardiovascular ICU who appeared to comprise the intervention group. No indication of how the control group were selected or groups were assigned. Insufficient information (poster) to permit judgement.	**Not clear** – Insufficient information to permit judgement, particularly on dressing application, standard pressure ulcer prevention strategies, and staff applying the dressings and conducting the skin assessments.	**Not clear** – Outcome measures vague (signs and symptoms of pressure ulcer development) and no specific details of skin assessment. Skin assessments conducted on a daily basis until discharge from ward. Insufficient information to permit judgement.	**Not clear** – Inclusion criteria specified some confounding factors but patient characteristics were not reported. Insufficient information to permit judgement.	**Not clear** - Patients were reported to be similar in terms of age, BMI and history of diabetes but no statistical tests were applied. Insufficient information to permit judgement.	**Not clear** - No details on any patients lost to follow-up. Insufficient information to permit judgement.	**Not clear** - No confidence intervals or p values stated. Insufficient information to permit judgement	Poster only – limited information Power calculations not reported Small sample size in the intervention group; sample size of control group not reported Mölnlycke Health Care provided poster support

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Park 2014 (Park et al. 2014)	**Not clear** - Clear inclusion and exclusion criteria were applied to patients admitted to 1 of 2 medical ICUs at the same hospital. No details of how patients were assigned to the intervention and control groups.	**Not clear** – Insufficient details of how the dressings were applied, although primary wound nurses from both intervention and control wards were shown the correct method of application. Patients in both groups received the same pressure ulcer preventive care regimen.	**Not clear** – Outcome measures were defined. Nurses acting as data collectors were taught how to evaluate skin status and stage pressure ulcers. Skin assessments based on NPUAP 2009 guidelines were conducted every 3 days for the duration of the study (9 days). Blinding not possible due to nature of the treatments and unclear whether the same nurses assessed patients in both groups.	**Yes** – Some confounding factors were discussed in the introductory section of the article, whilst study methodology described the evaluation of a range of potential risk factors.	**Yes** - Chi-squared or independent group t-tests were used to analyse homogeneity of the 2 groups in terms of a wide range of potential risk factors.	**Yes** – All patients follow-up and accounted for in the analysis.	**Not clear** – p-values reported but no confidence interval for the primary outcome.	Higher proportion of males in the intervention group (71% vs 56%). Power calculation reported Small sample size

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Richard-Denis 2017 (Richard-Denis et al. 2017)	**Not clear** - Patients admitted to a level-1 trauma centre following a spinal cord injury between April 2010 and March 2016. Minimal inclusion criteria. Patients in the intervention and control groups were recruited over sequential time periods which corresponded to changes in pressure ulcer prevention protocols. It was unclear why the groups were imbalanced in terms of patient numbers.	**No** – Insufficient details of how the dressings were applied or the staff involved. All patients received the same standard care, with the exception that patients in the dressing group had gel pads placed to replace the use of a mattress as part of standard care.	**Not clear** - Outcome measure was defined. Pre-operative skin assessment was every 8 hours in dressing group but unclear post-operatively. Timings unclear in gel mattress group. Pressure ulcer development and staging was based on clinical practice guidelines (NPUAP 2007) Follow-up was until discharge from acute care.	**Yes** – 12 potential risk factors were identified and reported.	**Not clear** – Potential risk factors were compared between groups using multivariate logistic regression and discussed. The intervention group used an alternative to gel mattress as part of standard care and this was not considered in interpretation of the results.	**N/A** – Retrospective study of prospectively collected data.	**Not clear** – p-values presented but not confidence intervals for primary outcomes	Retrospective study of prospective cohort with the 2 interventions studied over consecutive time periods at a single site The groups were imbalanced in terms of patient numbers: 286 (gel mattress) vs 89 (dressing) Power calculation not reported

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Santamaria 2015a (Santamaria et al. 2015a) (BORDER II)	**Yes** - Potential participants were all major trauma and critically ill patients who were admitted to the emergency department then transferred to ICU. Exclusion criteria were reported Patients were matched on most variables.	**Not clear** – Insufficient details of how the dressings were applied or the staff involved. Data for the control group was taken from another trial and it was unclear whether standard pressure ulcer prevention strategies were the same in both groups.	**Not clear** – Outcome measure defined but unclear assessment procedures. Prospective observation of intervention group based on daily skin assessments until patients were ambulant or left the ICU. Pressure ulcers identified and staged using AWMA definitions, and all researchers had undergone inter-rater reliability testing. Data for control group obtained from another trial, for which assessment methods and timings were not reported.	**Not clear** – Minimal discussion of confounding factors. A broad range of demographic, physiological and clinical characteristics was reported. Length of stay in the ICU was highlighted as being an important factor.	**Not clear** - Confounding factors were considered when comparing baseline characteristics of the two] groups, standard care defined and comparable in both groups. Authors discussed differences in LOS between the 2 groups as a limitation of the study	**Not clear** – Flow chart shows all stages of patient follow-up, with losses to follow-up clearly reported under. Insufficient breakdown of differences in drop-outs between the 2 groups.	**Not clear** – p-values presented but confidence intervals not reported	Prospective study with retrospective control (Border I trial) conducted over different time periods. Power calculation reported disparity in ICU length of stay between the 2 groups Study funded by Mölnlycke Health Care

Study name (acronym)	Was the cohort recruited in an acceptable way1?	Was the exposure accurately measured to minimize bias2?	Was the outcome accurately measured to minimize bias3?	Have the authors identified all important confounding factors?	Have the authors taken account of the confounding factors in the design and/or analysis	Was the follow-up of patients complete?	How precise (for example, in terms of confidence interval and p value) are the results	EAC Comments
Yoshimura 2016 (Yoshimura et al. 2016) (BOSS trial)	**Yes** - Bilateral comparison of 2 types of dressing applied to the same patient. Patients were selected according to clear inclusion and exclusion criteria.	**Not clear** – Insufficient details of how both types of dressings were applied and by whom, although the standard positioning protocol used for all patients was described in full.	**Not clear** - Outcome measure defined. Skin assessments were conducted 30 minutes after surgery completed, based on NPUAP 2014 guidelines used, with results confirmed by 2 nurses. Blinding not possible as each person received both types of dressing, 1 to each side of chest. All patients followed-up (timings not reported) for pressure ulcers by review of the medical records for at least 1 week (the time during which a deep tissue injury might occur).	**Yes** – A range of patient and operational risk factors were identified and reported.	**Yes** – Operation factors were addressed in the design of the study, and risk factors for pressure ulcer s were assessed and analysed	**Yes** – Flow chart shows complete follow-up of all patients, with no loss to follow-up	**Not clear** – p-values reported. Confidence intervals only reported for relative risk values.	Bilateral comparison study of 2 types of dressing, applied to chest and iliac crest in the same patient. No power calculation reported.

Abbreviations: AMWA, Australian Wound Management Association; BMI, body mass index; ICU, intensive care unit; LOS, length of stay; NDNQI, National Database of Nursing Quality Indicators; NPUAP, National Pressure Ulcer Advisory Association; WOC, wound, ostomy and continence.

[1] Cohort recruitment was considered acceptable providing sufficient detail on the selection and similarity of patients had been reported by the authors.
[2] The exposure was considered accurately measured if the procedure for applying the dressing is sufficiently detailed, the same procedure was carried out for all of the patients, and the dressings were applied by similar experience level hospital staff. In addition, the intervention and comparator groups should have received the same level of standard care.
[3] The outcomes were considered accurately measured providing they (and their measurements, including assessment timings) were clearly defined by the authors, based on established guidelines or equivalent validated scales.

Grey shading indicates that the paper is available as an abstract/poster only.
Yellow shading reflects information submitted under 'academic in confidence' and corresponding EAC comments on this study.

Appendix F: Issues identified by the EAC with the company's report of results

Study	Issues identified by the EAC
Aloweni 2017 (Aloweni et al. 2017)	In Table B9.1 of the submission, the company did not state that the study reports per protocol analyses in addition to ITT.
Kalowes 2016 (Kalowes et al. 2016)	In Table B9.2 of the submission, the company did not specify clear outcome measurement units. In this case, the units are "Incidence: Number of patients with pressure ulcers (%)" and "Incidence rate: n / 1000 days". The percentage for incidence, which is reported in the study publication, was also missing.
Santamaria 2015a (Santamaria et al. 2015a)	In Table B9.3 of the submission, the data reported for overall pressure ulcer incidence is not relevant to the scope. The overall incidence relates to pressure ulcers at both the sacrum and heel, which were treated using different dressings (Mepilex Border Sacrum and Mepilex Heel). Since Mepilex Heel is not an eligible intervention, only the separate data reported for Mepilex Border Sacrum is relevant.
Chaiken 2012 (Chaiken 2012)	In Table B9.10 of the submission, the company reported that the results were based on an ITT analysis. However, the authors do not explicitly state that this was the case in the study publication.
Haisley 2015 (Haisley et al. 2015)	In Table B9.15 of the submission, the company report that the results are based on an ITT analysis. However, the authors do not explicitly report that this was the case in the study publication.
Park 2014 (Park 2014)	In Table B9.22 of the submission, the company included and reported data for 2 outcomes (relating to incontinence associated dermatitis and its severity) that are not relevant to the scope.
Santamaria 2015b (Santamaria et al. 2015b)	In Table B9.24 of the submission, the company reported the number of patients allocated to the intervention and control groups. However, the number of patients analysed in each group was lower at 150 and 152 patients respectively. Further, the company reported that the study results were based on an ITT analysis. Whilst the authors do report in the publication that ITT analysis was carried out, the analysis population excluded patients who died, were discharged before the first assessment and lost to follow-up. Therefore, the integrity of the ITT analysis questionable.
Yoshimura 2016 (Yoshimura et al. 2016)	In Table B9.27 of the submission, the company reported results from the study relating to pressure ulcer incidence on the chest. This is not eligible to the scope. The study publication does report relevant results relating to pressure ulcer incidence at the iliac crest. However, these results were not presented in the company's table.
Abbreviations: ITT, intention-to-treat	

Appendix G: List of single arm studies not reporting device-related adverse event data

Studies
Pressure Injury Prevention in the ICU With Multi-Layer Foam Dressings. Identifier: NCT02962882. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicines: 2016. Available from https://ClinicalTrials.gov/show/NCT02962882.
Baker G. Nursing driving excellence: Preventing pressure ulcers in the high-risk population (poster presentation). In: Symposium on Advance Wound Care Fall, Las Vegas, Nevada, United States of America; 2014.
Brindle CT. Outliers to the Braden Scale: Identifying high-risk ICU patients and the results of prophylactic dressing use. WCET Journal. 2010;30(1):11-18.
Daukste M. Mepilex border sacrum dressing use for pressure ulcers prevention in period of open heart surgery and ICU. Cardiol. 2013;1:33.
Edwards MB, Lynch JH. Head over heels for prevention: Use of a silicone bordered foam heel dressing in the prevention of pressure ulcers (poster presentation). In: Symposium on Advanced Wound Care Fall, Las Vegas, Nevada, United States of America; 2014.
Gentry T, Wright A. The 'sacral heart' dressing study: Use of an absorbent self-adherent soft silicone sacral foam dressing across acute care settings (poster presentation). In: The Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomal Therapists, Phoenix, Arizona, United States of America; 2010.
Johnstone A, McGown K. Innovations in the reduction of pressure ulceration and pain in critical care. Wounds UK. 2013;9(3):80-84.
Lientz J. Dollars and sense: Economic value in HAPU/sDTI prevention (poster presentation). In: National Pressure Ulcer Advisory Panel Biennial Conference 2013: Houston, Texas, United States of America.
Muldoon C, Grossman N, Lawrence P. Initial use absorbent soft silicone self-adherent bordered foam dressing reduces sacral pressure ulcers in the cariovascular ICU (poster presentation). In: The Joint Conference of the Wound Ostomy and Continence Nurses Society and the World Council of Enterostomol Therapists, Phoenix, Arizona, United States of America; 2010.
Sullivan R. Use of a soft silicone foam dressing to change the trajectory of destruction associated with suspected deep tissue pressure ulcers. Medsurg nursing : official journal of the Academy of Medical-Surgical Nurses. 2015;24(4):237-42, 67.

Appendix H: Economic evidence: critique of company's search methods, details of re-run company's NHS EED search and PRISMA diagram

Critique of the company's search methods to identify economic evidence

The company's search methods to identify economic evidence were described in Section 10.3 Appendix 3 of the submission.

The searches conducted by the company to identify clinical evidence were also used to identify economic evidence. These search methods consisted of a search of MEDLINE and Embase and a search of 2 internal company sources. For the sources searched, it was appropriate to use 1 set of results for both clinical and economic evidence; the searches were not restricted by study design so would have retrieved both clinical and economic evidence. For a critique of these search methods please see Appendix A. As discussed in the critique, the methods had a number of limitations which may potentially have impacted on search sensitivity.

The MTEP submission template states that searches for economic evidence should include at least MEDLINE, Embase, MEDLINE In-Process, EconLit and NHS EED. In addition to MEDLINE (including In-Process records) and Embase, the company also searched NHS EED for the economic evidence search. The company did not search EconLit as they did not have access to it. In the absence of EconLit, the inclusion of an additional economic-specific search resource, for example the Cost-Effectiveness Analysis (CEA) Registry (freely available online for basic searches) could have enhanced the search methodology.

The reporting of the company's NHS EED search was limited in detail. Although the date of search was clear, no details were given on the interface used. Although a narrative description of the search was provided ("the database was searched on the title terms (pressure AND ulcer) which only resulted in 5 irrelevant papers"), the full search syntax (as displayed in a search interface) was not given. This made it difficult to be certain how the actual search was run. When the EAC used the description provided to approximate the same search in NHS EED, 15 records were retrieved. This anomaly accentuated the lack of clarity regarding how the NHS EED search was actually run.

The search strategy as reported in the submission for NHS EED search was limited, and not appropriate for a systematic literature search. The description indicated that the search was restricted to just those records where the search terms were found in the title field. This approach risked missing relevant records. The strategy lacked appropriate truncation. By not truncating '*ulcer*'

the company's strategy did not search on the term 'ulcers'. The range of terms used in the NHS EED search was also limited. Whereas the company's MEDLINE and Embase search strategies captured a range of variant terms for pressure ulcers (for example, bed sores, pressure sores, pressure injuries and decubitus ulcers), these terms were not included in the NHS EED search strategy. The lack of appropriate truncation and the limited range of terms potentially increased the risk of missing relevant records. Not restricting the search to titles, including appropriate truncation and including an appropriate range of variant terms in the NHS EED search would have enhanced search methodology.

The searches carried out by the EAC to identify clinical evidence (reported in Appendix A) were not restricted by study design and were prospectively designed to retrieve both clinical and economic evidence. The search sources included economics-specific databases (NHS EED, EconLit and CEA Registry). No additional *de novo* EAC literature search for economic evidence was therefore conducted.

Details of re-run company's NHS EED search

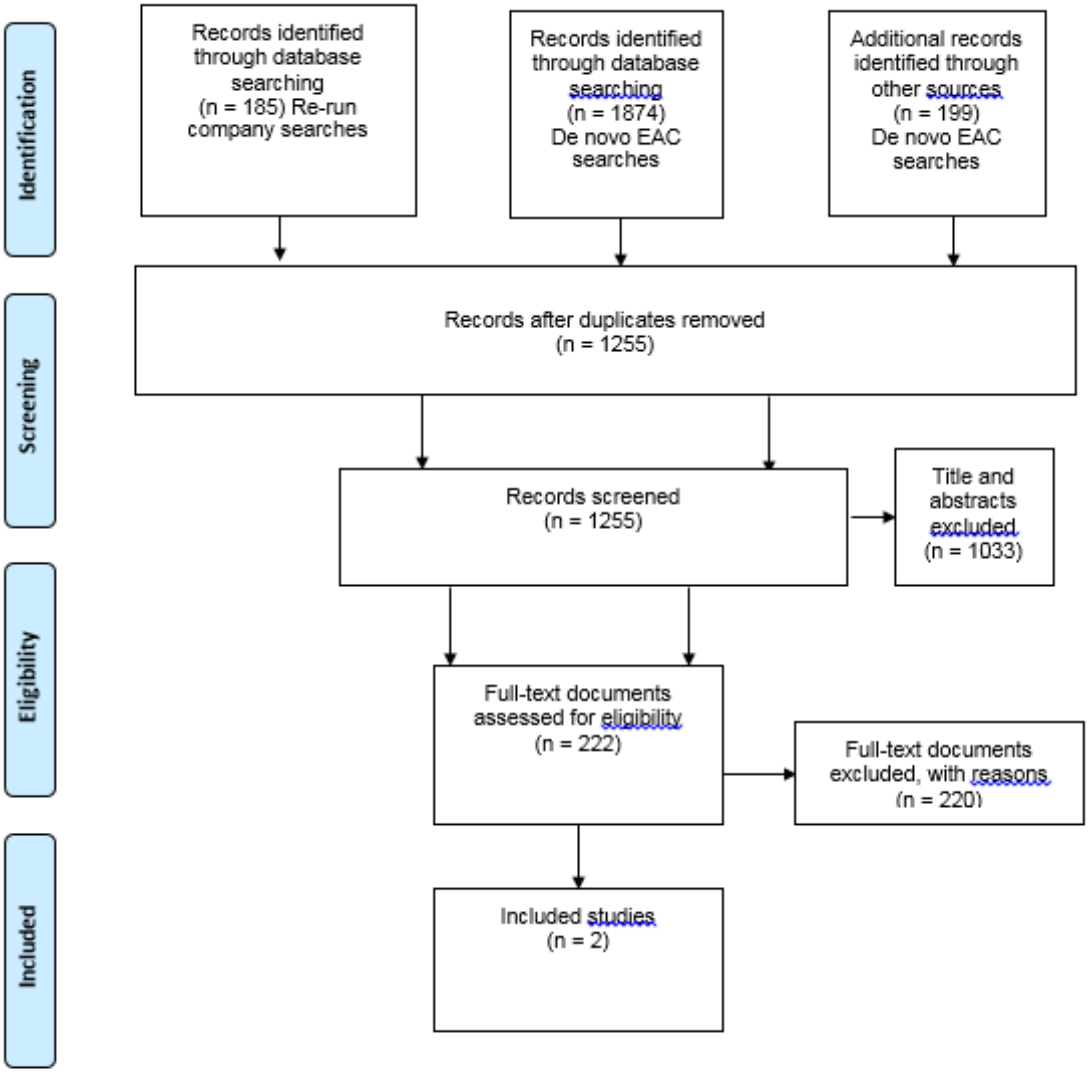
For details of the re-run company's searches in MEDLINE and Embase, see Appendix A. For details of the re-run company's search in NHS EED, please see below.

Re-run company's NHS EED search: full search strategy

1: Source: NHS Economic Evaluation Database
Interface / URL: https://www.crd.york.ac.uk/CRDWeb/HomePage.asp
Database coverage dates: Information not found. Bibliographic records were published on NHS EED until 31st March 2015. Searches for content were conducted up until the end of December 2014.
Search date: 20/04/18
Retrieved records: 15
Search strategy:

1	(pressure AND ulcer):TI IN NHSEED	15

PRISMA flow diagram showing studies assessed from the re-run company's clinical evidence searches, the EAC *de novo* searches and the re-run company's NHS EED search – Economics review



*records deduped against original and new search.

Appendix I: Drummond checklist on company model and submission

Study question	Response	EAC comments
1. Was the research question stated?	Yes	Decision problem set by NICE
2. Was the economic importance of the research question stated?	Yes	
3. Was/were the viewpoint(s) of the analysis clearly stated and justified?	Yes	Company states the analysis is from the NHS acute care perspective only.
4. Was a rationale reported for the choice of the alternative programmes or interventions compared?	Yes	Yes, in line with scope.
5. Were the alternatives being compared clearly described?	Yes	A clear description of Mepilex Border dressings is given in Section 2.1 of the company submission and standard care is described in Section 3.1 to 3.3.
6. Was the form of economic evaluation stated?	Yes	The company state a cost consequence approach is taken, however the EAC would argue a cost minimisation analysis has been undertaken as no consequences that have not been moneterised have been presented.
7. Was the choice of form of economic evaluation justified in relation to the questions addressed?	Yes	QoL gains would stem from the primary outcome of pressure ulcer reduction and input and resource use is readily available.
8. Was/were the source(s) of effectiveness estimates used stated?	Not clear	The company state a risk factor of early stent exchange for Memokath-051. It is not clear is this is a measure of effectiveness.
9. Were details of the design and results of the effectiveness study given (if based on a single study)?	Yes	Effectiveness inputs were taken from Santamaria (2015b) (Santamaria et al. 2015), and the study is described in Section 8.2.
10. Were details of the methods of synthesis or meta-analysis of estimates given (if based on an overview of a number of effectiveness studies)?	N/A	
11. Were the primary outcome measure(s) for the economic evaluation clearly stated?	Yes	Primary outcome was pressure ulcer incidence and associated cost of treatment.
12. Were the methods used to value health states and other benefits stated?	No	Whilst not strictly health states, the methods used to determine the incidence of pressure ulcer and the costs associated with pressure ulcer were discussed.

Study question	Response	EAC comments
13. Were the details of the subjects from whom valuations were obtained given?	N/A	
14. Were productivity changes (if included) reported separately?	N/A	
15. Was the relevance of productivity changes to the study question discussed?	N/A	
16. Were quantities of resources reported separately from their unit cost?	Yes	The company presented disaggregated costs for the intervention and by stage for the cost of pressure ulcer treatment
17. Were the methods for the estimation of quantities and unit costs described?	Yes	The quantities of resources for the intervention were estimated from a single trial. Unit costs were taken from national sources. Unit costs for pressure ulcer treatment were taken from an NHS tool.
18. Were currency and price data recorded?	Yes	Price year not completely consistent.
19. Were details of price adjustments for inflation or currency conversion given?	Not clear	
20. Were details of any model used given?	Yes	Decision tree structure
21. Was there a justification for the choice of model used and the key parameters on which it was based?	Yes	Reflects clinical pathway and pressure ulcer incidence is outcome of interest with cost or QoL impacts stemming from this.
22. Was the time horizon of cost and benefits stated?	Yes	Less than 1 year
23. Was the discount rate stated?	N/A	No discounting required
24. Was the choice of rate justified?	N/A	N/A
25. Was an explanation given if cost or benefits were not discounted?	Yes	Pressure ulcers expected to occur and heal within 1 year
26. Were the details of statistical test(s) and confidence intervals given for stochastic data?	No	
27. Was the approach to sensitivity analysis described?	Yes	Best and worst case scenarios presented and different incidence rates and dressing change frequencies tested in scenarios. Tornado diagram presented.

Study question	Response	EAC comments
28. Was the choice of variables for sensitivity analysis justified?	No	No justification provided. Baseline rate of pressure ulcer was not varied and no justification given.
29. Were the ranges over which the parameters were varied stated?	Yes	For 1-way sensitivity analysis they were, but not for scenario analyses.
30. Were relevant alternatives compared?	Yes	Compared with standard care which is consistent with the scope.
31. Was an incremental analysis reported?	Yes	In the model the company include an incremental analysis. In the report an incremental cost is given (Section, 9.5.2, Submission).
32. Were major outcomes presented in a disaggregated as well as aggregated form?	Yes	Presents technology cost, pressure ulcer treatment cost and staffing costs.
33. Was the answer to the study question given?	Yes	
34. Did conclusions follow from the data reported?	Some	The company compared the results of their analysis with a NICE Medtech Innovation Briefing, noting that their analysis estimates higher cost savings.
35. Were conclusions accompanied by the appropriate caveats?	Yes	The company noted the analysis is based on a single unblended RCT from an Australian setting, in which standard care was not defined. This study also included use of Mepilex Heel rather than Mepilex Border Heel.
36. Were generalisability issues addressed?	Yes	The company noted the analysis may not be generalisable to a paediatric or a community setting.
Adapted from Drummond MF, Jefferson TO (1996) Guidelines for authors and peer reviewers of economic submissions to the BMJ (59). Cited in Centre for Reviews and Dissemination (2008) Systematic reviews. CRD's guidance for undertaking reviews in healthcare. York: Centre for Reviews and Dissemination		

Appendix J: EAC search strategy for baseline pressure ulcer incidence and pressure ulcer treatment costs

A pragmatic search strategy was developed in Ovid MEDLINE to identify papers which report on the baseline risk and costs of pressure ulcers in the UK. The search retrieved 358 records for assessment.

The final strategy used is shown in Figure 1. The search was run on 20/04/18 in the following database: Ovid MEDLINE(R) Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>.

The strategy included 4 concepts:

- Pressure ulcers (search lines 1 - 5).
- Risk (search lines 6 - 19).
- Costs (search lines 20 – 40).
- UK (search lines 46 – 56).

The strategy was structured: pressure ulcers AND (risk OR costs) AND UK

The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the PubMed PubReminer tool (http://hgserver2.amc.nl/cgi-bin/miner/miner2.cgi). The terms for the baseline risk concept targeted records which explicitly referred to the following terms in the database record: risk, rate, likelihood, probability, incidence, prevalence or epidemiology.

The terms for the costs concept were based on the search filter developed by the University of York Centre for Reviews and Dissemination (CRD) for retrieval of economic evaluations for inclusion in the NHS EED database[5] (search lines 20 – 36). Given that the context for this search was retrieval of all studies reporting costs (not just economic evaluations) the CRD filter was expanded by the inclusion of additional cost-related terms (search lines 37 – 39).

The search also included search lines designed to identify records which are indexed with the Pressure Ulcer subject heading with attached economics or epidemiology subheadings (search lines 43 – 44).

[5] http://www.crd.york.ac.uk/crdweb/searchstrategies.asp#nhseedmedline

The strategy used the NICE UK search filter[6] to restrict to UK studies (search lines 46 – 56). This validated filter was developed by the NICE guidance Information Services team for use in Ovid MEDLINE to retrieve publications with a UK setting.

The strategy excluded animal studies using a standard algorithm. The strategy also excluded some publication types which were unlikely to yield study reports (news, comment, editorial, and letter). The strategy was restricted to studies published in English from 2012 to date.

The strategy was pragmatic. It was not designed to be exhaustive, but to target papers which were most likely to be relevant to the research question, and to retrieve result numbers which were manageable within the context of project timelines and resources

Figure 1: Search strategy for Ovid MEDLINE(R) In-Process & Other Non-indexed Citations and Ovid MEDLINE(R) <1946 to Present>

1	Pressure Ulcer/ (11301)
2	((pressure or deep tissue$ or decubit$) adj ulcer$).ti,ab,kf. (8618)
3	((pressure or deep tissue$ or decubit$) adj (sore$ or injur$ or lesion$)).ti,ab,kf. (3771)
4	(bedsore$ or bed-sore$).ti,ab,kf. (651)
5	or/1-4 (15460)
6	risk/ or risk assessment/ or risk factors/ (985513)
7	(risk or risks).ti,ab,kf. (1852601)
8	(rate or rates).ti,ab,kf. (2394617)
9	likelihood functions/ (20333)
10	likelihood.ti,ab,kf. (120534)
11	Probability/ (53374)
12	probabilit$.ti,ab,kf. (174778)
13	incidence/ (228750)
14	(incidence or incidences or incident or incidents).ti,ab,kf. (732790)
15	prevalence/ (250732)
16	prevalen$.ti,ab,kf. (636575)
17	epidemiology/ (12037)
18	epidemiolog$.ti,ab,kf. (362632)
19	or/6-18 (5246076)
20	Economics/ (26904)
21	exp "Costs and cost analysis"/ (214272)
22	Economics, dental/ (1892)
23	exp "Economics, hospital"/ (22779)
24	Economics, medical/ (8948)
25	Economics, nursing/ (3979)
26	Economics, pharmaceutical/ (2748)
27	(economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. (659699)

[6] National Institute for Health and Care Excellence (2016) MEDLINE UK geographic search filter

28	(expenditure$ not energy).ti,ab. (25332)
29	value for money.ti,ab. (1412)
30	budget$.ti,ab. (25449)
31	or/20-30 (801745)
32	((energy or oxygen) adj cost).ti,ab. (3657)
33	(metabolic adj cost).ti,ab. (1211)
34	((energy or oxygen) adj expenditure).ti,ab. (22076)
35	or/32-34 (26041)
36	31 not 35 (795748)
37	exp Budgets/ (13259)
38	exp models, economic/ (13181)
39	(econometric$ or financ$ or expens$ or expenditure$).ti,ab,kf. (214100)
40	or/36-39 (928207)
41	5 and 19 (6621)
42	5 and 40 (1713)
43	Pressure Ulcer/ep [Epidemiology] (1690)
44	Pressure Ulcer/ec [Economics] (375)
45	or/41-44 (7508)
46	exp Great Britain/ (343284)
47	(national health service* or nhs*).ti,ab,in. (152500)
48	(english not ((published or publication* or translat* or written or language* or speak* or literature or citation*) adj5 english)).ti,ab. (88673)
49	(gb or "g.b." or britain* or (british* not "british columbia") or uk or "u.k." or united kingdom* or (england* not "new england") or northern ireland* or northern irish* or scotland* or scottish* or ((wales or "south wales") not "new south wales") or welsh*).ti,ab,jw,in. (1805699)
50	(bath or "bath's" or ((birmingham not alabama*) or ("birmingham's" not alabama*) or bradford or "bradford's" or brighton or "brighton's" or bristol or "bristol's" or carlisle* or "carlisle's" or (cambridge not (massachusetts* or boston* or harvard*)) or ("cambridge's" not (massachusetts* or boston* or harvard*)) or (canterbury not zealand*) or ("canterbury's" not zealand*) or chelmsford or "chelmsford's" or chester or "chester's" or chichester or "chichester's" or coventry or "coventry's" or derby or "derby's" or (durham not (carolina* or nc)) or ("durham's" not (carolina* or nc)) or ely or "ely's" or exeter or "exeter's" or gloucester or "gloucester's" or hereford or "hereford's" or hull or "hull's" or lancaster or "lancaster's" or leeds* or leicester or "leicester's" or (lincoln not nebraska*) or ("lincoln's" not nebraska*) or (liverpool not (new south wales* or nsw)) or ("liverpool's" not (new south wales* or nsw)) or ((london not (ontario* or ont or toronto*)) or ("london's" not (ontario* or ont or toronto*)) or manchester or "manchester's" or (newcastle not (new south wales* or nsw)) or ("newcastle's" not (new south wales* or nsw)) or norwich or "norwich's" or nottingham or "nottingham's" or oxford or "oxford's" or peterborough or "peterborough's" or plymouth or "plymouth's" or portsmouth or "portsmouth's" or preston or "preston's" or ripon or "ripon's" or salford or "salford's" or salisbury or "salisbury's" or sheffield or "sheffield's" or southampton or "southampton's" or st albans or stoke or "stoke's" or sunderland or "sunderland's" or truro or "truro's" or wakefield or "wakefield's" or wells or westminster or "westminster's" or winchester or "winchester's" or wolverhampton or "wolverhampton's" or (worcester not (massachusetts* or boston* or harvard*)) or ("worcester's" not (massachusetts* or boston* or harvard*)) or (york not ("new york*" or ny or ontario* or ont or toronto*)) or ("york's" not ("new york*" or ny or ontario* or ont or toronto*))))).ti,ab,in. (1182316)
51	(bangor or "bangor's" or cardiff or "cardiff's" or newport or "newport's" or st asaph or "st asaph's" or st davids or swansea or "swansea's").ti,ab,in. (45547)
52	(aberdeen or "aberdeen's" or dundee or "dundee's" or edinburgh or "edinburgh's" or glasgow or "glasgow's" or inverness or (perth not australia*) or ("perth's" not australia*) or stirling or "stirling's").ti,ab,in. (173164)
53	(armagh or "armagh's" or belfast or "belfast's" or lisburn or "lisburn's" or londonderry or "londonderry's" or derry or "derry's" or newry or "newry's").ti,ab,in. (21411)
54	or/46-53 (2330389)

55	(exp africa/ or exp americas/ or exp antarctic regions/ or exp arctic regions/ or exp asia/ or exp australia/ or exp oceania/) not (exp great britain/ or europe/) (2567980)
56	54 not 55 (2206613)
57	45 and 56 (1145)
58	exp animals/ not humans/ (4448366)
59	(news or comment or editorial or letter).pt. (1796370)
60	57 not (58 or 59) (1098)
61	limit 60 to (english language and yr="2012 -Current") (360)
62	remove duplicates from 61 (358)

Key to Ovid symbols and commands

$	Unlimited right-hand truncation symbol
*	Unlimited right-hand truncation symbol
$N	Limited right-hand truncation - restricts the number of characters following the word to N
?	Wildcard symbol wild card character stands for zero or one characters within a word or at the end of a word
ti,ab,kf.	Searches are restricted to the Title, Abstract, or Keyword Heading Word fields
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other
/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
pt.	Search is restricted to the publication type field
or/1-4	Combines sets 1 to 4 using OR

Appendix K: EAC's sensitivity analysis

Ranges used for univariate sensitivity analysis

Model parameter	Base case value	Low value	High value	Rationale
Baseline risk of pressure ulcer with standard care	3.8%	2.5%	46.0%	Lowest (Walker et al. 2017) and highest values (Park 2014) identified in clinical review.
Relative risk of pressure ulcer with Mepilex Border Heel and Sacrum dressings	0.51	0.22	1.18	Confidence intervals identified in meta-analysis (see Section 3.6.2)
Mepilex Border dressings cost per patient	£57.52	£19.95	£88.15	Wide range used to vary number of dressings to capture uncertainty. Lower values of 1.5 Mepilex Border Sacrum dressings and 2 Mepilex Border Heel dressings and higher values of 5 Mepilex Border Sacrum dressings and 10 Mepilex Border Heel dressings used to calculate dressings costs.
Staff cost per patient	£12.33	£0.35	£14.00	Low and high values for dressings combined with low and high values for staff costs per minute (£0.42 based on average of bands 2 to 4, £0.83 based on average of bands 5 to 8a (Personal Social Services Research Unit (PSSRU) 2017)). Combined with low and high estimates of minutes required per dressing change (1.5 minutes, 3 minutes) based on clinical expert responses.
Pressure ulcer treatment cost – Mepilex	£4,823	£1,299	£15,097	Costs varied between cost of stage 1 pressure ulcer and stage 4 pressure ulcer (Dealey et al. 2012).
Pressure ulcer treatment cost – standard care	£4,823	£1,299	£15,097	Costs varied between cost of stage 1 pressure ulcer and stage 4 pressure ulcer (Dealey et al. 2012).

Distributions used for probabilistic sensitivity analysis

Parameter	Mean (SE)	95% CI	Alpha,Beta	Distribution type	Justification
RR of pressure ulcer with Mepilex Border dressings	0.51 (0.43)	0.22 to 1.18	NA	Lognormal	Confidence intervals used from meta-analysis (see Section 3.6)
Pressure ulcer incidence standard care	3.8% (0.02)	2.3% to 5.2%	24.02, 638.86	Beta	20% standard error assumed in order to produce wide variation to capture uncertainty.
Pressure ulcer treatment cost – Mepilex Border dressings	£4,823 (£2,412)	£2,932 to £6,714	25.00, 192.93	Gamma	20% standard error assumed in order to produce wide variation to capture uncertainty. This was varied independently for Mepilex Border and standard care arms in a scenario (see Figure 4.7).
Total cost of Mepilex Border dressings per patient	£58 (£17)	£20 to £88	10.93, 5.26	Gamma	Estimated low and high plausible values used for confidence intervals (see Section 4.2 EAC sensitivity analysis)
Cost of nurse time per patient	£12 (£9)	£2 to £37	1.91, 6.44	Gamma	Estimated low and high plausible values used for confidence intervals (see Section 4.2 EAC sensitivity analysis)